UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re PHILIP MORRIS INTERNATIONAL INC. SECURITIES LITIGATION	:	Master Docket No. 1:18-cv-08049-RA CLASS ACTION
This Document Relates To: ALL ACTIONS.	:	DEMAND FOR JURY TRIAL

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

TABLE OF CONTENTS

Lead Plaintiffs Union Asset Management Holding AG and Teamsters Local 710 Pension Fund (collectively, "Plaintiffs"), individually and on behalf of all other persons similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants (defined below), allege the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Philip Morris International Inc. ("Philip Morris" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants, who purchased or otherwise acquired the publicly traded securities of Philip Morris from July 26, 2016 through April 18, 2018, inclusive (the "Class Period"). Plaintiffs seek to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Philip Morris is one of the largest and most recognizable cigarette and tobacco manufacturing companies in the world. The Company's subsidiaries and affiliates and their licensees are engaged in the manufacture and sale of cigarettes and other nicotine-containing products in markets outside of the United States.

3. Cigarette sales have been declining worldwide for years. To combat these negative sales trends, the Company has in recent years been engaged in the development and commercialization of smoke-free alternatives to cigarettes. These products, known as reduced-risk products ("RRPs"), are marketed as safer and presenting a lower health risk than cigarettes. Philip Morris claimed that its "ambition is to lead a full-scale effort to ensure that non-combustible products ultimately replace cigarettes to the benefit of adult smokers, society, our company and our shareholders." The Company's flagship RRP, "iQOS," is a controlled device into which a specially designed heated tobacco unit (known as HEETS or HeatSticks) is inserted; the tobacco unit is then heated to generate an aerosol.

4. This case focuses on the transformative shift in Philip Morris's business model away from traditional cigarettes and Defendants' efforts to drive interest in iQOS through their aggressive and materially false and misleading statements about iQOS. As alleged herein, during the Class Period, Defendants made materially false and misleading statements about the clinical trials conducted by the Company in connection with its Modified Risk Tobacco Product Application ("MRTPA") to the U.S. Food and Drug Administration ("FDA") for iQOS, as well as the performance of iQOS in its primary market, Japan, in the wake of the FDA's rejection of Philip Morris's claim that iQOS is safer than cigarettes.

5. Following the initial roll-out of iQOS into Japanese markets in 2014, Philip Morris sought to expand its consumer base worldwide. As a key part of this expansion strategy, the Company submitted its MRTPA for iQOS to the FDA in December 2016. During the Class Period, Defendants repeatedly claimed that the clinical studies it sponsored in connection with the MRTPA showed that iQOS is less harmful than cigarettes.

6. As detailed more fully below, these statements were materially false and misleading because Defendants knew but failed to disclose, *inter alia*, that there were irregularities in the studies underpinning Philip Morris's applications to the FDA for iQOS in the United States. Half of these clinical studies were conducted in Japan, the very market where iQOS sales were first introduced. In addition, contrary to Defendants' representations, Philip Morris's clinical studies failed to comply with Good Clinical Practices and the Company failed to inform the market that there were at least 53 potentially harmful compounds in iQOS that did not exist in cigarettes. In other words, the chances of the FDA approving Philip Morris's application were much less likely than investors had been led to believe, and Defendants knew that.

7. On December 20, 2017, *Reuters* released an investigative report detailing irregularities in the clinical trials underpinning the Company's FDA application for iQOS in the United States. *Reuters* highlighted significant deficiencies within the clinical trials, such as tainted urine samples and significant shortcomings in the training and professionalism of the lead investigators, including the failure to follow basic procedure to obtain informed consent, and uninformed and unsophisticated investigators, among other concerns.

8. In response to this disappointing news, the Company's stock price fell $3.75 per share to close at $104.37 per share on December 20, 2017, eviscerating more than $5.8 billion in market capitalization.

9. Then, on January 25, 2018, the FDA's Tobacco Products Scientific Advisory Committee ("TPSAC") recommended the rejection of Philip Morris's bid to market iQOS as safer than traditional cigarettes in the United States. That same day, *The New York Times* published an article entitled "F.D.A. Panel Rejects Philip Morris's Claim That Tobacco Stick Is

Safer Than Cigarettes," reporting that the TPSAC Committee questioned the quality of the science behind the Company's safety claims, and in an eight-to-one vote, the "panel rejected the company's contention that 'scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.'"

10. In response to this news, the Company's stock price fell $3.11 per share to close at $107.49 on January 25, 2018, wiping out approximately $4.8 billion in market capitalization.

11. Following the revelation of the deficient iQOS clinical trials and the FDA's TPSAC recommendations, Defendants needed to assure investors that demand for iQOS had not waned and that it was still experiencing strong demand for iQOS in Japan – by far the Company's most important iQOS market. For example, Defendant Andre Calantzopoulous, Philip Morris's Chief Executive Officer, highlighted the supposedly "***increasing demand for HeatSticks, which we expect to grow further in the first quarter***." But, Defendants failed to disclose that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim, and that Philip Morris had already saturated the younger, easier-to-convert, iQOS user base and was struggling to get older, slower-to-change, cigarette smokers to switch to using the iQOS device in Japan.

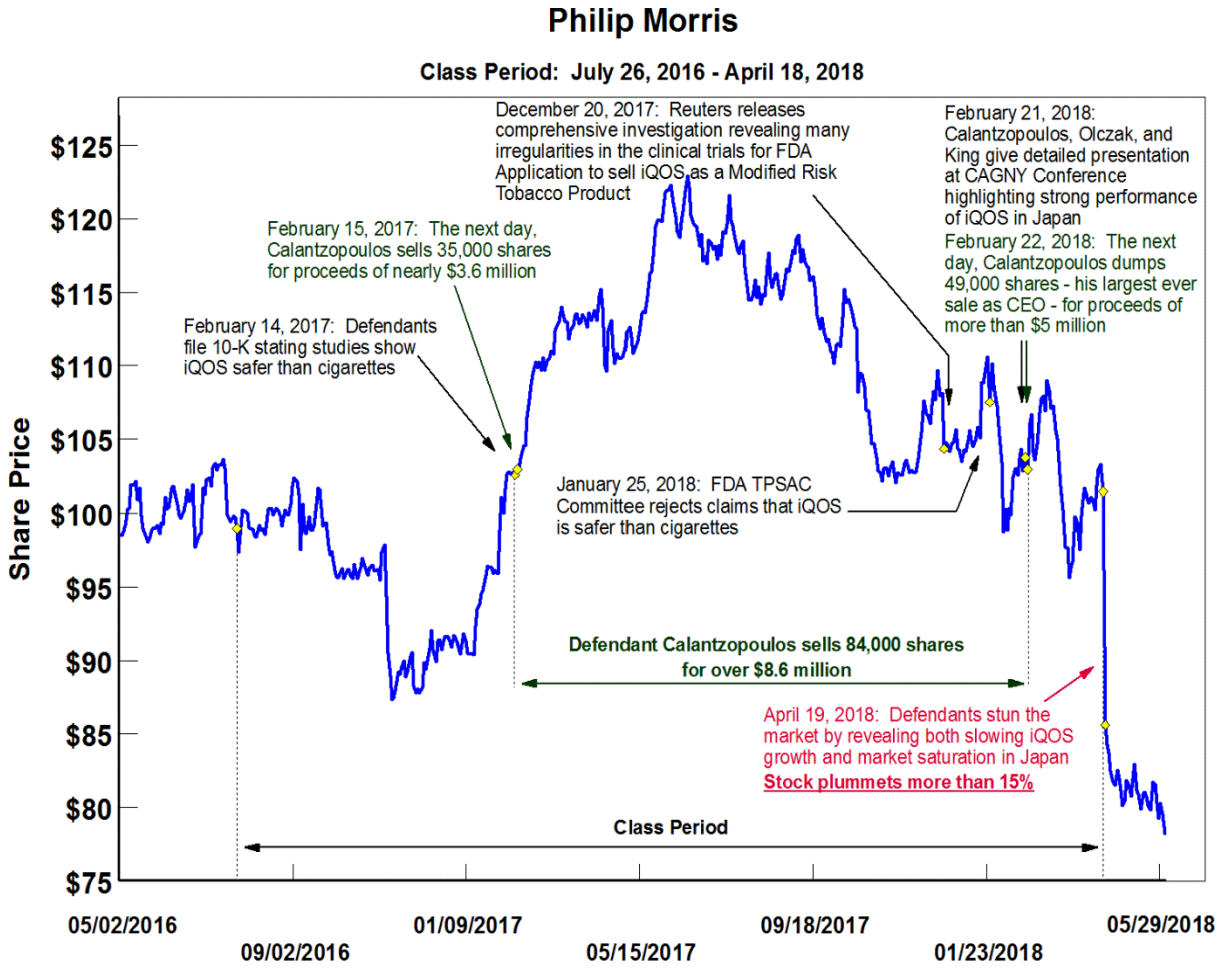
12. On April 19, 2018, in a stunning reversal from what Defendants had recently relayed to the market, Defendants disclosed that growth in iQOS sales had actually ***slowed*** in the very same Japanese markets that they had just highlighted as experiencing strong growth. In particular, Defendants announced that the Company's market share growth in Japan had hit a "plateau," and that Philip Morris was experiencing "less-rapid-than-initially-projected growth in sales of devices to consumers in Japan in the first quarter, as we are now reaching more

conservative adult smoker segments that may require, at least at first, slightly more time for adoption."

13. On this news, the Company's stock price plummeted $15.80 per share, or more than 15%, to close at $85.64 per share on April 19, 2018, on heavy trading volume. This represented the worst daily decline for the Company's stock in nearly a decade.

14. As a result of Defendants' materially false and misleading statements, Philip Morris securities traded at artificially inflated prices during the Class Period. After the above revelations seeped into the market, the price of Philip Morris common stock declined significantly, sending the Company's stock price down ***30%*** from its Class Period high.

15. Before the truth about the Company's deficient clinical trials and the performance of iQOS in Japan were revealed to the market, Defendant Calantzopolous and other senior Philip Morris executives cashed in, collectively selling over $31 million of their personally-held Philip Morris shares to the unsuspecting investing public at artificially inflated prices. Defendants' fraudulent scheme and the loss felt by investors are shown in the following graphic:



JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

17. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

18. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C §78aa) and 28 U.S.C. §1391(b), as the Company maintains its principal executive offices in the

United States, conducts business, and a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

19. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

20. Lead Plaintiff Union Asset Management Holding AG purchased Philip Morris securities during the Class Period as set forth in its previously filed certification, which is incorporated by reference herein, and was damaged thereby.

21. Lead Plaintiff Teamsters Local 710 Pension Fund purchased Philip Morris securities during the Class Period, as set forth in the certification attached as Appendix A, and was damaged thereby.

22. Defendant Philip Morris is a Virginia corporation with its principal executive offices in the U.S. located at 120 Park Avenue, New York, New York. Philip Morris, through its subsidiaries, manufactures and sells cigarettes, other tobacco products, and other nicotine-containing products. The Company's stock trades on the New York Stock Exchange ("NYSE") under the ticker symbol "PM."

23. Defendant André Calantzopoulos ("Calantzopoulos") has been the Chief Executive Officer ("CEO") of Philip Morris since May 8, 2013. Calantzopoulos served as Philip Morris's Chief Operating Officer from March 28, 2008, until his appointment as CEO. He joined the Company in 1985.

24. Defendant Martin G. King ("King") has served as Philip Morris's Chief Financial Officer ("CFO") since January 1, 2018. Before his appointment as CFO, King served as President of the Company's Asia region. He joined the Company in 2003.

25. Defendant Patrick Picavet ("Picavet") is Philip Morris's Director of Medical Affairs. Between August 2014 and January 2017, Picavet was Philip Morris's Director of Clinical Assessment. Commencing in February 2017, Picavet became the Company's Director of Medical Affairs and was responsible for the planning and execution of the Company's scientific studies on its smoke-free products, including iQOS.

26. Defendant Jacek Olczak ("Olczak") has served as Philip Morris's Chief Operating Officer ("COO") since January 1, 2018. Olczak also served as the Company's CFO during the Class Period until his appointment as COO. He joined the Company in 1993 as a Manager of Finance and Administration and was appointed CFO in August 2012.

27. Defendant Manuel C. Peitsch ("Peitsch") was Philip Morris's Chief Scientific Officer for Reduced-Risk Products during the Class Period.

28. Defendant Frank Lüdicke ("Lüdicke") was Philip Morris's Chief Medical Officer during the Class Period. He oversaw the Company's clinical trials for iQOS.

29. Defendants Calantzopoulos, King, Picavet, Olczak, Peitsch, and Lüdicke are sometimes referred to herein as the "Individual Defendants."

30. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the content of Philip Morris's reports to the SEC; press releases; documents posted by the Company on its official website; and presentations to securities analysts, money portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases

alleged herein to be misleading before, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material nonpublic information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

31. The Individual Defendants, together with Defendant Philip Morris, are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

A. Philip Morris's Efforts to Pedal Supposedly "Reduced-Risk" Products to Extract Profits

32. The vast majority of Philip Morris's sales derive from cigarettes, which include the Company's well-known and traditional brands such as Marlboro. Large tobacco manufacturers, however, have been under the threat of declining sales volumes for years, as the number of smokers has decreased globally, offset somewhat by population growth. Companies such as Philip Morris have branched out into alternative smokeless products, such as heated tobacco products, to increase sales volumes and market share. Philip Morris has spent ***over $4 billion*** developing these new smoking platforms and, as part of that initiative, has published its findings based largely on clinical and non-clinical studies. Between 2016 and 2017, the Company's total cigarette shipment volumes decreased from about 812.9 billion units to about 761.9 billion units. During this same time, sales of the Company's heated tobacco products increased from about 7.4 billion units to over 36.2 billion units. Thus, it was critically important

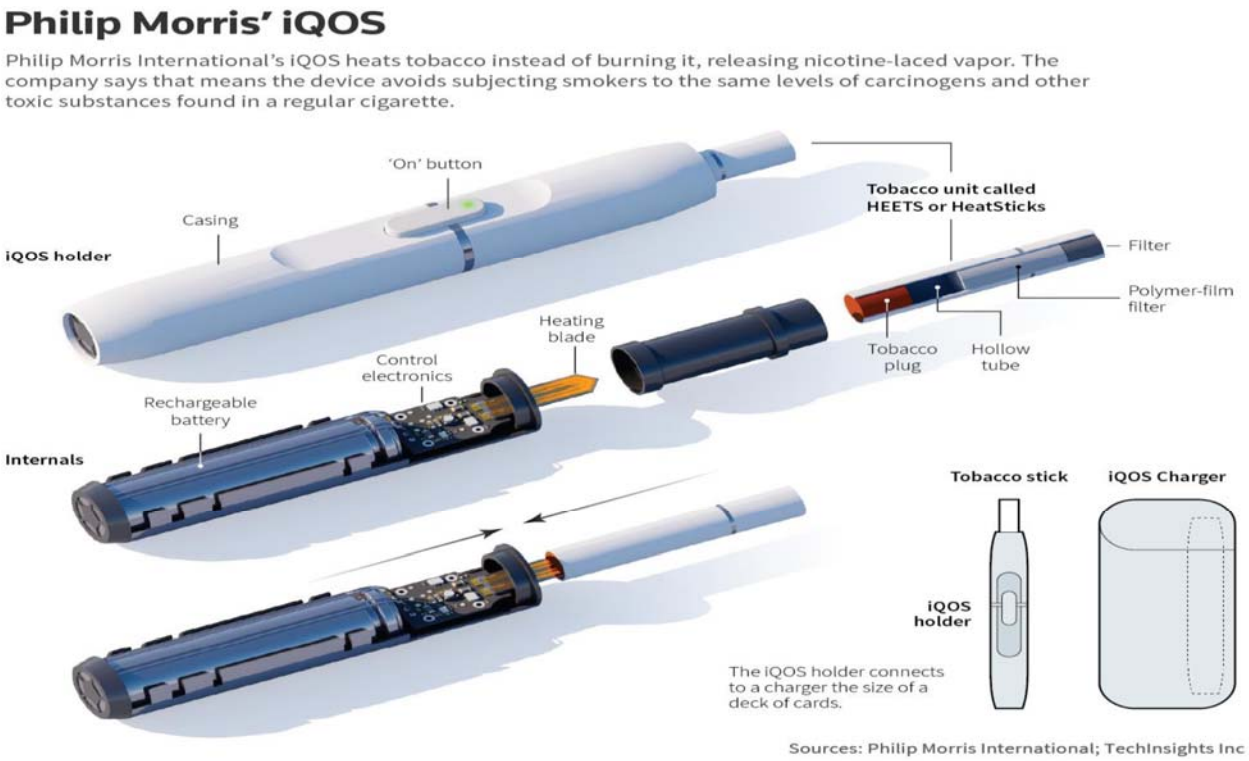
to investors and the Company's long-term prospects that Philip Morris stem the tide of lower cigarette sales volumes and continue to increase its heated tobacco unit sales volumes.

33. In September 2017, Philip Morris announced it had pledged up to $1 billion to launch a foundation dedicated to eliminating smoking worldwide. Upon making this announcement, Defendant Calantzopoulos told the *Financial Times* that "[o]ur efforts are squarely focused on ***ultimately replacing cigarettes with smoke-free products***, by offering the millions of men and women who continue to smoke a better alternative. We are standing at the cusp of a true revolution . . . ."

34. Philip Morris acknowledges the extent of this fundamental shift in the Company's business model on its website as follows:

> Now we've made a dramatic decision.
>
> We will be far more than a leading cigarette company. We're building PMI's future on smoke-free products that are a much better choice than cigarette smoking.
>
> Indeed, our vision – for all of us at PMI – is that these products will one day replace cigarettes.

35. The "smoke-free" product that the Company has bet its future on is called iQOS. iQOS is an electronic device that heats specially designed tobacco units – heating tobacco just enough to release a flavorful nicotine-containing vapor without combustion, fire, ash or smoke. iQOS contains three main components: a heated tobacco unit (called HEETS or HeatSticks), an iQOS holder and a charger.



36. Philip Morris claims that "[b]ecause the tobacco is heated and not burned, the levels of harmful chemicals are significantly reduced compared to cigarette smoke."

37. During the Class Period, Defendant Calantzopoulos repeatedly told investors and the media that he intended to replace cigarettes with iQOS: "I believe there will come a moment in time where I would say we have sufficient adoption of these alternative products ... to start envisaging, together with governments, a phase-out period for cigarettes," Calantzopoulos said in an interview on BBC Radio 4. "I hope this time will come soon," he added. Similarly, Manuel Peitsch, the Company's Chief Scientific Officer emphasized the importance of iQOS to the Company's future, telling investors that "[a]t PMI, our company's objective is clear: our future is in products that have been scientifically demonstrated to be less harmful than cigarettes. If our science is not credible, millions of smokers who might otherwise benefit from the alternatives we are developing might not do so."

38. iQOS was first introduced in the city of Nagoya, Japan in late 2014 and launched nationwide in Japan in the spring of 2016. During the Class Period, the success of iQOS in Japan was vitally important as it was the only country in which it was available nationwide.

39. In order to increase sales, Philip Morris promoted iQOS in Japan as a less harmful product than conventional cigarettes. This approach also helped persuade officials to classify the iQOS device differently than cigarettes, resulting in a lower tax rate and exempting it from ordinances banning smoking in public places.

40. Philip Morris's efforts to market RRPs began almost a decade earlier. For example, in November 2005, at a meeting with officials from Japan's Ministry of Health, Labor and Welfare ("MHLW"), Peter Nixon, Managing Director of Philip Morris International, lobbied the Japanese government against raising taxes and banning tobacco due to public health concerns, touting a product Philip Morris was developing that was meant to reduce the risk of tobacco-related diseases. Nixon made similar lobbying efforts again during a November 2008 meeting with MHLW officials, stating that Philip Morris is investing significant amounts of money in researching and developing RRPs, "a very high priority in our company's business." On September 21, 2016, Philip Morris's Japan representative attended the Second Kanagawa County Prevention of Passive Smoking in Public Facilities Regulation Review Meeting and lobbied the government officials for better regulatory treatment of iQOS, representing that Philip Morris has conducted clinical trials and that the heating device would be less harmful than conventional cigarettes.

41. As of January 2018, cigarettes in Japan were taxed at 60 percent, while the iQOS tobacco inserts were taxed lower, at 51 percent. According to Euromonitor International, the Japanese heat-not-burn cigarette market reached $5.3 billion in 2017, almost triple the size of the

prior year. Philip Morris held a 94% share of that market, where more than half of the world's iQOS users live.

42. Unlike in Japan, which lacked a rigorous regulatory framework, Philip Morris had to obtain the approval of the FDA to be able to sell iQOS in the United States, and for permission to market it as a Modified-Risk Tobacco Product ("MRTP"). The MRTP designation would permit Philip Morris to market iQOS in the U.S. as presenting less harm or risk of disease to users than traditional tobacco. The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), signed into law on June 22, 2009, provides the FDA with authority to regulate the manufacture, distribution, and marketing of tobacco products. The law also puts in place specific restrictions on marketing tobacco products to children and gives the FDA authority to take further action in the future to protect public health.

43. Defendants have stated that Philip Morris's ability to sell iQOS in the United States as an MRTP is conditioned upon the FDA's approval and that the FDA's approval will also impact the regulatory approach of other jurisdictions. For example, Defendants have explained that "[w]e expect that future FDA actions are likely to influence the regulatory approach of other interested governments."

44. Section 2(40) of the Tobacco Control Act states that "[t]he dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that [FDA must] ensur[e] that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product." The Tobacco Control Act requires manufacturers to "demonstrate that such products . . . meet a series of rigorous criteria and will benefit the health of the population as a whole" before marketing tobacco products for use to reduce harm or the risk of tobacco-related disease or to reduce exposures to harmful substances

associated with tobacco products. Accordingly, the FDA has issued Draft Guidance for MRTPA, which advises the applicant seeking FDA approval to "includ[e] information both favorable ***and*** unfavorable to the ability of the product to reduce risk or exposure and relating to human health." (Emphasis in original). In the case of an application for a risk modification order, the MRTPA must provide robust scientific evidence to demonstrate that the product significantly reduces harm and the risk of tobacco-related disease to individual users. *See* § 911(g)(1)(A) of the FD&C Act and Draft Guidance.

45. In December 2016, the Company submitted an MRTPA to the FDA for iQOS. In May 2017, the FDA formally accepted and filed the Company's MRTPA for substantive scientific review.[1]

46. Philip Morris submitted its FDA application under Section 911(g) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") requesting market orders under both § 911(g)(1) (risk modification order) and § 911(g)2) (exposure modification order) for its Tobacco Heating System ("THS") to be marketed as iQOS. The Company explained that it was submitting its application for THS as a MRTP with three different variants, Marlboro *HeatSticks*, Marlboro Smooth Menthol *HeatSticks*, and Marlboro Fresh Menthol *HeatSticks*.

47. Section 911(g)(1) of the FD&C Act provides that the FDA may issue a modified risk market order for a tobacco product if the sponsor satisfies a two-prong test. The applicant must demonstrate that the product "as it is actually used by consumers, will (a) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (b) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products."

[1] Philip Morris entered into an agreement with Altria Client Service LLC ("ALCS") pursuant to which ALCS or its operating companies have a license to distribute and sell iQOS in the U.S.

48. Philip Morris claimed that its application provided the necessary information supporting a marketing order for an MRTP with the following three claims:

- Claim 1 under § 911(g)(1): "Switching completely from cigarettes to the iQOS system can reduce the risks of tobacco-related diseases."
- Claim 2 under § 911(g)(1): "Switching completely to iQOS presents less risk of harm than continuing to smoke cigarettes."
- Claim 3 under § 911(g)(2): "Switching completely from cigarettes to the iQOS system significantly reduces your body's exposure to harmful and potentially harmful chemicals."

49. In connection with the MRTPA, Philip Morris asserted that "the weight of the evidence that THS significantly reduces harm and the risk of tobacco-related disease to individual tobacco users is compelling" and is supported by scientific studies.

50. The Company also outlined the "seven-step approach" it used to assess whether iQOS poses less risk of harm or disease than conventional cigarettes:

> **Product design and control principles**
>
> The first step of the assessment is designed to ensure that a given smoke-free product is manufactured to appropriate quality standards and is sufficiently characterized to document product performance parameters. This product characterization enables the establishment of a product specification, which all products entering the subsequent assessment steps must meet, as must the products that are introduced to the market. In this initial phase, PMI verifies that the product's design is likely to result in a significant reduction in risk for smokers who switch to it and that it does not pose any additional risks to those already known for cigarettes. Realizing the risk reduction potential of a smoke-free product relies on the quality of the product design and on strict manufacturing controls to ensure that the product operates consistently and reliably.
>
> **Aerosol chemistry and physics**
>
> We analyze the chemical composition of the aerosol generated by the smoke-free product to quantify the reduction in formation of harmful and potentially harmful constituents in comparison with a cigarette. We also evaluate whether new potentially harmful constituents are generated by the smoke-free product and confirm the absence of combustion in aerosol generation.

Standard toxicology assessment

Once a product has been developed, we use robust laboratory techniques to evaluate whether a product is less toxic than cigarette smoke. We do this by assessing whether it causes less damage to cells and organs using in vitro and in vivo techniques.

Systems toxicology assessment

We use highly sophisticated laboratory techniques to assess the effect of switching to a smoke-free product on the development of smoking-related disease in comparison with smoking and cessation. Our systems toxicology program allows us to compare the effects of switching with those of cessation on the molecular-level disease mechanisms caused by smoking. This is achieved by measuring the changes in gene, protein and metabolite levels caused by switching and cessation in comparison with continued smoke exposure and analyzing this data using advanced computational methods.

Clinical studies

We conduct clinical studies with adult smokers according to the principles of Good Clinical Practice. These studies help us understand whether switching to a smoke-free alternative reduces a smoker's exposure to toxicants compared with on-going smoking. We also determine whether this leads to a reversal of clinical risk markers linked to smoking-related diseases. These studies compare the effects in continued smoking, switching and quitting cigarettes for the duration of the studies. *This phase is fundamental to help substantiate claims*. (Emphasis added)

Perception and behavior studies

Our program of Perception and Behavior Assessment studies is aimed at developing understandable and scientifically accurate consumer messages; assessing the comprehension of these messages and the risk perception of the smoke-free product among various adult consumer groups; and assessing the suitability of the smoke-free product as a substitute for cigarettes among adult smokers.

Post-market studies and surveillance

Once a smoke-free product is on the market, we conduct post-market studies to understand how the product is used and by whom. Our aim is to ensure that the product does not attract significant numbers of never and former smokers, but does lead to a significant portion of current adult smokers switching to it completely. Additional clinical studies are conducted to determine the health outcomes of switching to the product compared with ongoing smoking and to cessation.

51. In addition to non-clinical studies, the Company represented that it conducted eight clinical studies supporting claims under §§ 911(g)(1) and (g)(2) of the FD&C Act. As reflected in Philip Morris's FDA application, the clinical studies are described in the table below and were conducted between 2013 and 2015:

THS Clinical Assessment

Study Code and Clinicaltrials.gov ID	Study Type	Investigational Product	Comparators Groups	Duration of Exposure
ZRHR-**PK-01-EU** NCT01967732	PK/PD	THS	CC; NRT (NNS)	Single use
ZRHR-**PK-02-JP** NCT01959607	PK/PD	THS	CC, NRT (nicotine gum)	Single use
ZRHM-**PK-05-JP** NCT01967706	PK/PD	mTHS	mCC, NRT (nicotine gum)	Single use
ZRHM-**PK-06-US** NCT01967719	PK/PD	mTHS	mCC, NRT (NNS)	Single use
ZRHR-**REXC-03-EU** NCT01959932	Reduced Exposure	THS	CC; SA	5 days in confinement
ZRHR-**REXC-04-JP** NCT01970982	Reduced Exposure	THS	CC, SA	5 days in confinement
ZRHM-**REXA-07-JP** NCT01970995	Reduced Exposure	mTHS	mCC, SA	90 days (5 days confinement and 85 days ambulatory)
ZRHM-**REXA-08-US** NCT01989156	Reduced Exposure	mTHS	mCC; SA	90 days (5 days confinement and 86 days ambulatory)

Abbr.: CC = Conventional Cigarette, EU = European Union, ID = Identification, JP = Japan, mCC= mentholated conventional cigarette, NNS = Nicotine Nasal Spray, NRT = Nicotine Replacement Therapy, PD = Pharmacodynamic, PK = Pharmacokinetic, SA = Smoking Abstinence, THS = Tobacco Heating System, mTHS = menthol version of THS, US = United States of America

52. In conducting the clinical trials for iQOS, Philip Morris defined its objectives as follows:

- to develop RRPs that adult smokers who would otherwise continue to smoke find to be satisfying alternatives to smoking;
- for those adult smokers, our goal is to offer RRPs with a scientifically substantiated risk reduction profile that approaches as closely as possible that associated with smoking cessation;
- to substantiate the reduction of risk for the individual adult smoker and the reduction of harm to the population as a whole, based on scientific evidence of the

highest standard that is made available for scrutiny and review by external independent scientists and relevant regulatory bodies; and

- to advocate for the development of science-based regulatory frameworks for the development and commercialization of RRPs, including the communication of scientifically substantiated information to enable adult consumers to make better health choices.

53. Philip Morris represented that its clinical studies were registered and available on the public website ClinicalTrials.gov, a U.S. government database managed by the National Institute of Health. The Company also claimed that it "remain[s] committed to sharing the results of [its] research with the public and the scientific community."

B. Philip Morris Repeatedly Represented that Its iQOS Studies Complied with Good Clinical Practices

54. During the Class Period, Philip Morris repeatedly emphasized that its clinical studies "are conducted according to Good Clinical Practice ("GCP")." On its official website, the Company claimed that its clinical studies "are conducted by experienced Contract Research Organizations ("CROs"), and that "[a]ll of our clinical studies comply with the internationally recognized requirements of the International Conference of Harmonization's Good Clinical Practice." "This dictates the quality standards for designing, conducting and reporting our studies, as well as for protecting the safety and well-being of study-participants." Philip Morris told investors that the results of its clinical trials on iQOS "***provide evidence to substantiate both a reduced risk claim . . . and a reduced exposure claim***," and stated that the ***"totality-of-the-evidence presented," including the results of its clinical studies, "demonstrates that smokers who completely switch from cigarette smoking to THS should have a significant reduction in harm and the risk of tobacco-related diseases***."

55. Philip Morris acknowledged that "accurate and non-misleading communication of a product's risk reduction potential is a critical element to facilitate the switching of adult

smokers from cigarettes to RRPs." The Company underscored that "[w]hile there is growing support for tobacco harm reduction, there continues to be significant skepticism about the credibility of the tobacco industry and its ability to conduct sound science that can benefit public health."

56. According to the Guideline for Good Clinical Practice (the "Guideline"), "[GCP] is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that . . . the clinical trial data are credible." "The objective of th[e] ICH[2] GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions." The Guideline "was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO)." The Guideline "should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities." "The principles established in th[e] guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects."

57. The Guideline defines a "clinical trial" or a "clinical study" as "[a]ny investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s) . . . with the object of ascertaining its safety and/or efficacy." An "investigator" is defined as "[a] person responsible for the conduct of the

[2] ICH stands for the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator." "Protocol" is defined as "[a] document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial . . ."

58. According to the Guideline, "[c]linical trials should be scientifically sound, and described in a clear, detailed protocol," and "[e]ach individual involved in conducting a trial [including the investigators] should be qualified by education, training, and experience to perform his or her respective task(s)." The investigator "should have adequate resources to properly conduct the trial," "should be thoroughly familiar with the appropriate use of the investigational product(s), as described in the protocol . . . and in other information sources provided by the sponsor," and "should be aware of, and should comply with, GCP and the applicable regulatory requirements." "The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor . . . ." Moreover, the "investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor [of the clinical studies] in the CRFs [Case Report Forms] and in all required reports." In its clinical studies of iQOS, Philip Morris acknowledged that "[t]he Principal Investigator was responsible for ensuring that the study adhered to ICH GCP requirements."

59. The Guideline also requires the "Sponsor" of the clinical studies (*e.g.*, Philip Morris) to be "responsible for implementing and maintaining quality assurance and quality control systems with written SOPs [Standard Operating Procedures] to ensure that trials are conducted and data are generated, documented (recorded) and reported in compliance with the

protocol, GCP, and the applicable regulatory requirement(s)."[3] "Quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly."

60. While "a sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO [Contract Research Organization]," the Guideline states that the "ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."

61. Accordingly, it was critical for Philip Morris to conduct rigorous scientific studies that complied with GCP and accurately disclose the results of its studies and any related non-conformities.

C. Defendants Knew But Failed to Disclose Significant Irregularities in the Scientific Studies Forming the Basis of Philip Morris's FDA Application

62. As part of their investigation, Counsel for Plaintiffs interviewed Tamara Koval, a former Company scientist, whose job at the time the iQOS clinical trials were conducted included co-writing the protocol for the clinical studies globally and coordinating between Philip Morris and those contracted to run its iQOS clinical trials. At the Research and Development ("R&D") offices of Philip Morris, Koval worked with a team of employees who were preparing and managing the clinical trials conducted on smokers of iQOS, to ensure that the principal investigators and researchers were following GCP in their studies. She was part of the Product Assessment Group ("PASS Group"). The clinical trials were designed to prove the safety of iQOS over cigarettes and to comply with FDA regulations that went into effect in 2009. Koval worked at the Company's headquarters in Neuchatel, Switzerland from 2012 to January 2015 as

[3] The Guideline defines "Sponsor" as "[a]n individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial."

a Clinical Program Manager-Medical Officer. She travelled to the U.S. and other countries on behalf of Philip Morris.

63. The eight iQOS clinical trials that Philip Morris relied on in its application to the FDA were conducted in the U.S., Europe and Japan, between 2013 and 2015. Half of the eight studies were done in Japan. European countries and Japan allowed products like iQOS to be marketed and sold to consumers without undergoing rigorous testing.

64. According to Koval, Philip Morris saw iQOS as its next generation product. Philip Morris's senior management, *i.e.*, Bruno Chamielec, PMI's marketing director, and Defendants Picavet, the Director of the PASS Group and Frank Lüdicke, the Chief Medical Officer, told Koval and her colleagues in R&D that the Company's goal was to market iQOS in the U.S. by 2016, after clearing FDA approval. The team leading the effort to obtain FDA approval to market iQOS included defendants Picavet and Lüdicke. According to Koval, "[h]e and Patrick decided everything for the PASS Group," and Picavet also had ultimate responsibility for developing the clinical study protocol. They reported to the Company's Steering Committee who met monthly and established how much to spend on the clinical trials and their timeline. "Patrick talked to the Steering Committee all the time," said Koval, and he was present at every step of the clinical development program. The Steering Committee, chaired by Bertrand Bonvin, the Senior Vice President of R&D, included representatives from different departments, *e.g.*, marketing, legal, operations, product development, and the director, senior director, and Vice President of the clinical (PASS) department. Among other matters, the Steering Committee discussed iQOS's clinical development program (including the clinical studies) as well as timelines for placing the product into the U.S. market. Like Koval, Picavet

and Lüdicke worked in Philip Morris's Switzerland Neuchâtel office. Defendant Calantzopoulos worked in the Lausanne office, one hour away from Neuchâtel. Bonvin reported to the CEO.

65. Plaintiffs are also relying on an investigation conducted by *Reuters*, who interviewed six of the 11 principal investigators responsible for five of the eight clinical trials, and who identified significant shortcomings and irregularities in the iQOS trials. *Reuters* also interviewed Koval.

1. Contrary to Defendants' Representations, the Clinical Trial Investigators Were Unqualified and Lacked Adequate Resources

66. According to FDA guidelines for conducting clinical studies, a trial should adhere to GCP, pursuant to which investigators "should be qualified by training and experience and should have adequate resources" to properly conduct a trial.

67. Koval told Plaintiffs' Counsel and *Reuters* that several researchers and principal investigators were not fluent in English and therefore could not have understood the training they received on how to conduct the clinical trials and employ the protocol for conducting the trials, as the training and development were conducted in English with no translators present. Koval said that the quality of some of the researchers and sites contracted to carry out those experiments was deficient. Among other roles, Koval conducted medical safety training across the world for principal investigators and others involved with the iQOS studies. During one study training session in Tokyo, Koval said that she realized some of the investigators could not speak English and she was unable to communicate with them. Koval said she does not speak Japanese and there was no interpreter present. "I was like, Jesus, what are we doing here?" she said. Later at dinner, Koval said, she saw two of the men, and they were unable to describe in English what their jobs were. Koval explained that at these training meetings, it was both customary and imperative for the investigators to understand the study protocol and ask

numerous questions about such protocol. She explained that because the investigators did not speak English, and no interpreters were present, there was no way to ensure that the investigators were collecting blood and urine samples, or conducting data analysis, correctly. There were no questions or comments by the investigators at these training sessions. Koval said the training sessions are a critical milestone in product development, of which the clinical trials are a part. Koval emphasized that she has never before in her career encountered a situation where the principal investigators were unable to communicate with the safety officers training the investigators on the appropriate protocol. Koval said that she participated in more than a dozen principal investigator meetings during the course of her career and never before had zero questions been asked about the development or application of the protocol.

68. When asked by *Reuters* about Koval's session, Philip Morris said it was a meeting with its contract research organization and others and that "all PIs [principal investigators] and team members with active roles in the study were fluent in English." But Sugimoto, one of the Japanese principal investigators, told *Reuters* in an interview, "I can't speak English." And Endo, another of the lead researchers, told *Reuters* that when Philip Morris executives visited his site, someone was present to help translate "questions like whether to cut the crusts off bread" when giving food to study subjects.

69. Koval's depiction of unqualified investigators running iQOS's clinical trials was corroborated by the interviews conducted by *Reuters*. For example, a principal investigator for one of the clinical trials told *Reuters* that he doesn't hold such company-sponsored clinical trials in high regard, describing them as "dirty" because their purpose is more commercial than scientific.

70. Another principal investigator, Masayuki Sugimoto, who oversaw testing at one facility used by Philip Morris to conduct one of the iQOS clinical trials, told *Reuters* that his Tokyo clinic is "heavily in the red." Sugimoto also told *Reuters* that he generally has little confidence that all the participants in experiments like the one he ran for Philip Morris on nicotine tell the truth about their smoking history, *i.e.*, whether they smoke. *Reuters* reported that the Japanese company hired to monitor the clinical studies conducted in Japan, CMIC Holdings Co Ltd., said in a statement that researchers confirmed that trial participants were smokers by using urine tests. Asked about the tests, Sugimoto told *Reuters* that he thought they would prevent non-smokers from joining the trial but added, "I don't know whether they were done that rigorously." Tom Eissenberg, who served on the FDA's tobacco products scientific advisory committee from 2011 to 2017, told *Reuters* that Sugimoto's comments "raise[] a great deal of concern." According to Eissenberg, the people involved in the clinical trial must satisfy the requirements set forth in the protocol, *i.e.*, if the protocol required, as here, the subjects of the clinical trial to be smokers, the principal investigator must confirm that the participants are in fact smokers: "a PI should have confidence in that," he said.

71. Speaking about the final study report from the Philip Morris trial, Sugimoto also told *Reuters* that he generally doesn't have time to read such things in detail. He said he probably signed a document indicating he had received the final report. According to *Reuters*, Sugimoto gestured with his thumb and forefinger to indicate a thick document: "I just don't read them."

72. *Reuters* reported that at another laboratory in Japan, issues with how the study was carried out were so acute that data from 56 participants was thrown out, raising questions about the competence of the principal investigator. Philip Morris halted the study at that

location. In the Company's study documentation released by the FDA, Philip Morris recorded the reason for discarding the data as non-compliance with GCP, specifically "failure of the site to meet sample collection procedures and data recording procedures." Kishor Lad, who was Philip Morris's data manager on the study and worked at Philip Morris from 2012 to 2015, said the site crossed a line of what's allowed during such trials: it collected samples before getting informed consent forms signed by the volunteers. "Completely a no-no in the GCP world," Lad said. Philip Morris confirmed to *Reuters* that informed consent was not obtained before collecting urine samples. Greg Koski, a former director of the U.S. federal Office for Human Research Protections, which advocates for research subjects, said this incident "suggests the investigator had no idea, did not understand or just didn't care what his responsibilities were in conducting the study." According to Koski, "[t]his is such a flagrant violation, that investigator shouldn't be doing clinical studies."

73. Mamoru Oki was the principal investigator at the time at the facility, the Seishukai Clinic in Tokyo. Reached by phone, Oki told *Reuters*: "My specialty is urology and I don't know anything about tobacco, so I cannot talk." Replying to *Reuters*, Philip Morris insists that "Dr. Oki was qualified and trained specifically on the product." Dorothy Hatsukami, a member of the FDA's tobacco products scientific advisory committee from 2010 to 2013, explained that a principal investigator's professed lack of knowledge about tobacco is extremely troubling: "For any tobacco-related clinical trial, an investigator with a background in tobacco product research would have better qualifications to evaluate the study results than a novice," she said. *Reuters* reported that the study continued at a parallel site, the Tokyo Heart Center and that during an interview at the center, principal investigator Masahiro Endo said repeatedly that he had no idea what the results were from his study: "We did medically safe and accurate blood

samples, but were not told the results. So even if we are asked questions, we won't be able to answer," he said. "We were paid, it ended there." But, as reported by *Reuters*, in a statement signed last year and submitted by Philip Morris to the FDA, Endo said he had read the clinical study report which contained the study's results from the Company and confirmed that "to the best of my knowledge it accurately describes the conduct and results of the study." Principal investigators in all of the Philip Morris clinical trials signed the same statement.

74. Former FDA commissioner David Kessler, a clinical trial expert interviewed by *Reuters* in connection with its Philip Morris clinical trials investigation, said "[i]t seems like the investigator here is in the role of a technician, not as a principal investigator." Kessler further explained that it is hard to understand how such investigators could have signed off on the clinical study report "when they clearly were not versed in the study results."

2. Philip Morris's Own Scientists and Researchers Disagreed With Philip Morris's Public Representations That iQOS Is Less Harmful Than Cigarettes

75. Koval participated in strategy meetings with Bonvin, and the Senior Vice President of Product Development, who reported directly to Defendant Calantzopoulos. Koval said Defendant Calantzopoulos was kept informed of the status of the clinical trials through regular communications with the Senior Vice President. During the strategy meetings, senior management (*e.g.*, Bonvin, Picavet, and Peitsch) and Koval discussed the timeline for the clinical trials, their status, the resources, the need for more test subjects and the possibility of introducing the products in different markets. Koval emphasized that there was significant pressure from senior management to get the clinical trials done quickly so iQOS could make its debut in the U.S. market quickly. "The pressure came from senior management, *i.e.*, Bonvin, Lüdicke, and Picavet, to prepare our product to go to market by February or March 2016 in order to get market share," Koval said.

76. Koval noted that none of the eight iQOS clinical studies lasted more than 12 months. Some studies were even as short as just ***five*** days. Koval explained that in order to determine whether a new tobacco product is not harmful and whether such claims can be substantiated with evidence, clinical studies need to run for a long time, at least four years. Koval said that studies of short duration, such as the iQOS studies, are insufficient to show or make a representation of less risk of disease because developing a disease takes time. Koval also explained that the biomarkers on which Philip Morris focused would not have demonstrated less risk of disease because, *inter alia*, Philip Morris only looked at selective biomarkers, even the biomarkers analyzed by the Company did not conclusively demonstrate less risk of disease, and the mechanism for developing tobacco-related diseases is not clear.[4] Koval explained that, based on the short-term results, Philip Morris's clinical trials for iQOS showed that some of the biomarkers decreased, but the length of the trial was insufficient for those results to have any real meaning.

77. Koval said she was skeptical about receiving FDA approval. For example, Koval said the clinical trials were designed with an insufficient number of test subjects, and the length of the trials should also have been much longer in order to demonstrate that iQOS was a safe product.

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[4] Philip Morris defines biomarkers in the following manner: "Biomarkers can be classified into biomarkers of exposure and clinical risk markers.

• Biomarkers of exposure: indicate exposure to a potentially hazardous substance. In our case, the biomarker may be a cigarette smoke constituent or metabolite that is measured in a biological fluid or tissue and that can provide a measure of internal dose (i.e., the amount of the constituent taken up into the body);

• Clinical risk markers: a measurable biochemical, physiological, behavioral, or other alteration within an organism that, depending upon the magnitude, can be recognized as associated with an established or possible health impairment or disease."

78. Four scientists and researchers who worked for Philip Morris on the iQOS program similarly told *Reuters* that proving iQOS users are less exposed to harmful substances than cigarette smokers doesn't necessarily mean that using iQOS is less likely to result in disease than regular cigarettes. For example, Hans-Joerg Urban, who worked as a scientist at Philip Morris until 2010 analyzing data from clinical and laboratory experiments, told *Reuters* that "[e]xposure is not directly linked to the risk of having a disease." "The diseases are much too complicated." Dorothy Hatsukami, a former member of the FDA's tobacco products scientific advisory committee, told *Reuters* that she agrees with Mr. Urban. "At this point, research is still too nascent to say with certainty that reduced exposure translates into reduced risk," she said. Kishor Lad also told *Reuters* that to prove that iQOS presents less risk of tobacco-related disease, the Company would need to conduct large clinical trials over several years to demonstrate that people who used iQOS lived longer than those who smoked cigarettes. Lad added that it is not correct to say that "if you're less exposed to these harmful substances then, sort of, it's less harmful for you."

79. Despite the fact that the Company's own scientists and researchers concluded that less exposure to harmful components is not indicative of less risk of harm or disease, Philip Morris repeatedly mislead the public and represented that iQOS was less harmful than cigarettes.

3. Invalid Urine Samples Were Used in the Polish iQOS Study

80. As reported by Koval to Plaintiffs' Counsel and to *Reuters*, urine samples collected as part of one clinical study in Japan exceeded the limits of what a human being can produce in a single day, invalidating the results produced there. According to Koval, several subjects reported 12-18 liters of urine, when the normal urine samples produced by humans are between 2-4 liters. The subjects were healthy and there was no normal explanation for the abnormally large amount of urine collected. Similarly, Lad told *Reuters* that urine samples may

have been swapped or there was a problem with the containers used to collect the urine. When the principal investigator for this study, Katarzyna Jarus-Dziedzic, was asked about the results, she would not admit there was problem, instead claiming that the test subjects were large Polish men, Lad and Koval said.

81. Koval said that Picavet and the PASS Group were informed of these irregularities and that she was on the call when Picavet learned about these deviations in protocol, which were violations of data integrity. Koval explained that she communicated her concern to the PASS Group, but instead of addressing them, Picavet removed her from the matter. Picavet told Koval that it was not a "safety" concern but a concern for "operations." "I told Patrick that this is my responsibility because my signature is on all the documents," Koval said. In 2014, Philip Morris terminated her contract. After leaving Philip Morris, Koval was given a certificate of service that said, "Tamara drove clinical program development activities." It said she had demonstrated "professionalism" and "unwavering commitment" in her work.

82. Koval explained that the irregularities she identified in the clinical protocol were a "huge issue" and said that the samples should not have been used in the study. Philip Morris included the tainted samples in the full analysis.

4. Contaminated Urine Samples Were Used in the Japan Study

83. Koval identified another significant GCP violation in a clinical study conducted in Japan, where urine samples were collected and aggregated in one jar, leading to contamination. The study involved 120-180 subjects and was a Phase 3 clinical study that commenced in August 2013 and was completed in July 2014. This contamination was a violation of GCP because no conclusive analysis of components could be made on such contaminated samples. Koval explained that it was too late for Philip Morris to discard the study and commence recruitment of a large group of subjects in time for the submission of the FDA application. Thus, the analysis

was performed on the full set of the collected samples, *i.e.*, the contaminated urine samples were included in the study.

84. Koval explained that over 100 urine samples from a single day were contaminated. This contamination was significant because the study only ran for a short 5-day duration, meaning 20% of the total length of the study involved contaminated samples, which Philip Morris used to support its FDA application. The Company listed the study as evidence for its claim that iQOS is less harmful than conventional cigarettes. The Company did not disclose this GCP violation.

D. Philip Morris Hid Adverse Results from Four Scientific Studies That Refuted Claims Regarding the Safety of iQOS

85. During the Class Period, Philip Morris conducted at least four additional scientific studies whose results contradicted the Company's claim that iQOS is less harmful than cigarettes and was detrimental to the Company's FDA application to market iQOS as a reduced-risk product. These results were concealed from investors for a large part of the Class Period and were only submitted to the FDA in a late December 8, 2017 amendment—one year after the Company submitted its initial application to the FDA. Each of these studies was commenced *before* Philip Morris's FDA application was ever made and two of the studies had already concluded half a year *before* that submission. Two of the studies covered the period March 2016 - June 2016 and the remaining two covered the period October 2016 - January 2017. The latter studies, covering the period October 2016 – January 2017 were similar to the first two studies, covering the period March - June 2016, and their objective was to demonstrate that no new hazards are presented to users of THS2.2 [iQOS] compared with conventional cigarettes (collectively, the "Four Undisclosed Studies"). It is unclear why the first two studies were rerun.

86. According to a former employee who worked at Philip Morris during the Class Period, was involved in the Company's iQOS trials, and was familiar with the time it takes for the results of such studies to be available internally at Philip Morris, the results of the Four Undisclosed Studies were evident when the studies ended, *i.e.*, as early as June 2016 (or at most three weeks thereafter) for the first two studies and as early as January 2017 (or at most three weeks thereafter) for the remaining two studies, yet they were concealed from the FDA and investors. As these studies negated Philip Morris's claim that iQOS is less harmful than cigarettes, they should have been disclosed promptly. Instead, Philip Morris waited a year and a half to share the studies with the FDA and the public.

87. When the FDA finally received the studies in December 2018, many months after they were conducted, the FDA concluded that they showed "***additional aerosol testing information indicating there were compounds of toxicological concern present in higher quantities in HeatSticks aerosols than in reference cigarette smoke***." For example, the first study (P1 MRTPA RLS-ZRH-2016-76-82 LC-HRAM-MS, "Study 1") identified 13 compounds with significantly higher yields than the regular conventional reference cigarette and 16 compounds with significantly higher yields than the menthol conventional reference cigarette. The second study (P1 MRTPA RLS-ZRH-2016-75 GCxGC-TOFMS, "Study 2"), which used a different analytical method from the first study, identified a total of 42 compounds with significantly higher yields compared to the regular conventional reference cigarette and a total of 45 compounds with significantly higher yields compared to the menthol conventional reference cigarette. For both of these studies, Philip Morris conceded: "It was demonstrated that constituents present [highlighted] in the FDA list of 93 HPHCs[5] [17] (Study 1) and [18] (Study

[5] "HPHCs" are Harmful and Potentially Harmful Constituents.

2) were not significantly elevated in THS2.2 compared to 3R4F [conventional reference cigarette]." Accordingly, these studies also reflected that 17-18 of the FDA's list of 93 HPHCs showed the same elevation as in conventional cigarettes. The studies were silent on the remaining 76-77 HPHCs.

88. As with Studies 1 and 2, the "goal" of Studies 3 and 4 was to demonstrate that no new HPHCs were present in the aerosol of THS 2.2 in significantly higher concentrations than in the smoke of 3R4F. The third study (P1 MRTPA RLS-ZRH-2016-403-404 LC-HRAM-MS, "Study 3") identified 20 compounds with significantly higher yields in THS 2.2 menthol compared to the conventional reference cigarette, and the fourth study (P1 MRTPA_RLS-ZRH-2016-401_GCxGC-TOFMS, "Study 4"), using a methodology different from the third study, identified 44 compounds with significantly higher yields in THS 2.2 menthol than the reference cigarette. For Studies 3 and 4, Philip Morris conceded: "It was demonstrated that constituents highlighted in the FDA list of 93 HPHCs [17] (Study 3) and [18] (Study 4) were not significantly elevated in THS 2.2 compared to 3R4F [conventional reference cigarette]." In other words, these studies also reflected that 17-18 of the FDA's list of 93 HPHCs showed the same elevation as seen in conventional cigarettes. The studies were silent on the remaining 76-77 HPHCs.

89. These Four Undisclosed Studies squarely contradicted Philip Morris's claims and instead indicated that the analysis conducted did not show a significant improvement of HPHCs in iQOS over conventional cigarettes. Moreover, these studies showed that a significant number of toxic or potentially toxic compounds were found in aerosol that were not found in conventional cigarettes.

E. Philip Morris Contradicted and Silenced Independent Researchers Who Found High Toxins in iQOS

90. According to an article in the *Washington Post* dated August 11, 2017, one independent study examining the risks of iQOS found higher levels of several toxic compounds produced by the device than Philip Morris had claimed. The study was conducted by three Swiss researchers. The study compared the harmful compounds in the air generated by iQOS with those of regular cigarettes and found that, although iQOS generated many toxic chemicals at lower rates, some were much higher than Philip Morris claimed. It also found that iQOS produced 295 percent more of one hazardous compound than traditional cigarettes. The study found that volatile organic compounds, polycyclic aromatic hydrocarbons, and carbon monoxide were present in iQOS smoke. According to the study, the smoke released by iQOS contains elements from pyrolysis[6] and thermogenic degradation that are the same harmful constituents of conventional tobacco cigarette smoke. The results of this study were consistent with the Four Undisclosed Studies that showed elevated levels of toxic compounds from iQOS as compared to cigarettes.

91. A spokeswoman for the University of Lausanne, where one of the Swiss researchers works, explained in an email to a *Washington Post* reporter that after their study was published, the bosses of all three researchers received an alarming letter from Philip Morris. The letter was addressed to the heads of the University of Bern, Lausanne University Hospital and University of Lausanne, accusing their employees of faulty methodology.

92. Such a threatening letter is almost unheard of in the scientific community, University of Lausanne spokeswoman Francine Zabano said. If someone disagrees with a study,

[6] Pyrolysis is the thermal decomposition of materials at elevated temperatures in an inert atmosphere. *See Compendium of Chemical Terminology*, International Union of Pure and Applied Chemistry. (2009, at p. 1824).

they contact the journal where it was published or challenge its findings by publishing their own evidence.

93. As reported by the *Washington Post*, when informed of Philip Morris's letter to the researchers' employers, Mitchell Katz, deputy editor of the journal JAMA Internal Medicine, which published the study, said: "That certainly smacks of intimidation. I've been deputy editor here eight years, and I've never seen that happen before."

F. The FDA Advisory Panel Meeting and the FDA's Recommendation to Reject Philip Morris's Application

94. Philip Morris's scheme to mislead investors about the purported "benefits" iQOS has over conventional cigarettes became more apparent after an FDA advisory panel found the relevance of some of the Company's analytical data "unclear" and unsupportive of its claims that iQOS reduces risks of harm or disease, with voting members expressing concerns "about other risks that may be unique to iQOS that haven't been presented or characterized" and evidence showing higher quantities of toxic compounds in iQOS than in conventional cigarettes.

95. Pursuant to FDA regulations, the FDA is authorized to convene an Advisory Panel consisting of industry experts to opine on whether a particular product should be approved. The FDA exercised this option with respect to Philip Morris's iQOS application and scheduled a meeting of the Tobacco Products Scientific Advisory Committee ("TPSAC Meeting") for January 24 and 25, 2018.

96. In advance of the TPSAC Meeting, the FDA published its Briefing Document[7] on December 22, 2017, detailing its preliminary findings regarding the Company's application to market iQOS as an MRTP in the United States and the studies that were conducted. Its

[7] An FDA Briefing Document is a package containing background information prepared by the FDA for the panel members of the Advisory Committee. It contains assessments and/or conclusions and recommendations written by the individual FDA reviewers.

conclusions were bleak. The Briefing Document revealed numerous flaws in Defendants' studies.[8] With respect to Philip Morris's tests and analysis on product chemistry, the Briefing Document concluded that "[a] full characterization of the chemical composition of the aerosol produced by the *IQOS* is unknown." While the levels of some compounds formed by combustion and pyrolysis would be lower in the aerosol generated by iQOS than in combusted cigarettes, the Briefing Document stated that "other compounds would still be expected to be present in the aerosol. These compounds could include, but are not limited to, compounds produced by the pyrolysis of glycerol and propylene glycol and evaporated at temperatures less than 350°C; compounds transferred intact from the *IQOS* system to the aerosol by evaporation; and pesticides that are not burned and evaporated at temperatures less than 350°C." The Briefing Document noted poignantly that in an amendment to its applications, which Philip Morris did not submit to the FDA until December 8, 2017, "the applicant identified between 53 and 62 compounds that are at higher levels in the aerosol of the *HeatSticks* compared to the smoke of the reference cigarette 3R4F."

97. Discussing Philip Morris's non-clinical studies with respect to HPHCs and aerosol constituents, the FDA concluded that consuming 10 HeatSticks exposes users to levels of several carcinogenic and possibly carcinogenic compounds that are comparable to smoking 1-3 cigarettes. The FDA noted that in the Four Undisclosed Studies, "the applicant provided

[8] The Briefing Document included "a summary of the specific issues FDA identified during scientific review to date for which [the FDA was] specifically seeking recommendations from TPSAC, as well as the key issues and topics for discussion at the meeting." The Briefing Document also disclosed that its "conclusions and recommendations do not necessarily represent the final position of the individual reviewers, nor do they necessarily represent the final position of the Review Division or Office . . . The FDA will not make its determination on the issues at hand until input from TPSAC and from the public comments has been considered and all FDA reviews have been finalized."

additional aerosol testing information indicating there were compounds of toxicological concern present in higher quantities in *HeatSticks* aerosols than in reference cigarette smoke."

98. In the Briefing Document, the FDA also discussed Philip Morris's claim that its clinical studies provided further scientific support for the Company's application, finding that while "[t]he reduced exposure studies demonstrated minor improvements in some of the BOPHs [biomarkers of potential harm chosen by Philip Morris] in the *IQOS arm*, relative to continued smokers," "the significance of the changes is uncertain . . . substantial differences were not observed during the 90 days of exposure. This may be because the chosen markers were not observed long enough, were not tobacco-specific, or were not adequately sensitive to detect changes in physiology. It is not clear how predictive the chosen biomarkers are of long-term tobacco-related disease risk." The Briefing Document also called into question "the credibility of BOPHs as surrogate endpoints or substitutes for disease endpoints," observing that "[i]n other settings, biomarkers used as validated surrogate endpoints often fail to predict the clinical outcome of interest."

99. The TPSAC Meeting was held on January 24 and 25, 2018 at the FDA's offices in Silver Spring, Maryland. Over the course of the two days, the nine-member TPSAC voting panel heard numerous presentations from various Philip Morris representatives including Defendant Peitsch and Moira Gilchrist, the Company's Vice President of Scientific and Public Communications. Several experts also gave presentations on behalf of the FDA to report their analyses of Philip Morris's studies and MRTP application, including, *inter alia*, chemists, toxicologists and pharmacologists that reviewed the Company's submission. In addition, numerous speakers from an array of interest groups gave presentations to the TPSAC committee offering their position on the Company's application to sell iQOS in the United States.

100. At the TPSAC Meetings, the committee members echoed the concerns expressed in the Briefing Document. For example, one committee member, Dr. Weitzman, remarked:

> So the word that 'studies have shown," I don't see a whole lot of studies. For me, I'd feel very uncomfortable making a judgment call that what we've seen, it suggests, it implies, but I wouldn't, could not, under oath, say that what we've seen demonstrates to the scientific community that it's been shown.

101. Another committee member, Dr. Ossip, expressed similar skepticism:

> We have seen that with some of the biomarkers that there were very little differences between the HeatSticks or the iQOS and the combustible product. There's the comparison about 10 HeatSticks are about the equivalent of one to three referent cigarettes on a number of constituents that are carcinogenic or potentially carcinogenic. We know that there are some numbers somewhere between 53 and 60 constituents, if I'm remembering that correctly, that were higher in the HeatSticks compared to the combustible cigarettes or the referent cigarette, I think, and so there are a lot of unknowns here.
>
> And so I struggle with this, I think I'm - - you know, that term 'leap of faith' is really resonating for me, and maybe in combination with that, independent versus industry-sponsored studies.
>
> * * *
>
> I'm concerned about other risks that may be unique to iQOS that haven't been presented or characterized.

102. At the conclusion of the two-day TPSAC Meeting, the Committee held a lengthy discussion regarding the numerous presentations and then called a vote on several questions concerning the Company's submission. These questions included, *inter alia*, the following:

> 1. Discuss evidence related to the health risks of the IQOS system and the appropriateness of the proposed modified risk information.
>
> a. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases."? (Vote)
>
> **Yes – 0 No – 8 Abstain – 1**

b. Has the applicant demonstrated that the following statement in their proposed modified risk labeling and advertising is true: "Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes."? (Vote)

Yes – 4 No – 5 Abstain – 0

2. Discuss evidence regarding the likelihood that existing combusted cigarette smokers will initiate use of the IQOS system, completely switch to IQOS, and/or become long-term dual users of IQOS and combusted cigarettes.

a. What is the likelihood that that U.S. smokers would completely switch to use of the IQOS system? (High/Medium/Low)

High – 0 Medium – 2 Low – 7 Abstain – 0

5. Discuss evidence regarding consumer comprehension and perceptions of the proposed modified risk labeling and advertising.

a. Has the applicant demonstrated that, after viewing the proposed modified risk labeling and advertising, consumers accurately understand the risks of IQOS use as conveyed in the modified risk information? (Vote)

Yes – 0 No – 9 Abstain – 0

103. Accordingly, a majority of the Committee voted, *inter alia,* that: (i) the applicant failed to demonstrate that its scientific studies have shown that switching completely from cigarettes to the iQOS system can reduce the risks of tobacco-related diseases; and (ii) the applicant failed to demonstrate that switching completely to iQOS presents less risk of harm than continuing to smoke cigarettes.

104. After the TPSAC Committee's vote, on January 25, 2018, *The New York Times* published the article referenced above, entitled "F.D.A. Panel Rejects Philip Morris's Claim That Tobacco Stick Is Safer Than Cigarettes," reporting the Committee's recommendation for the rejection of Philip Morris's bid to market iQOS as safer than traditional cigarettes in the United States. According to the article, the Committee questioned the quality of the science behind the Company's safety claims, and in an eight-to-one vote, the "panel rejected the company's

contention that 'scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.'"

105. On this news, the Company's stock price fell from $110.06 per share to $107.49 per share on January 25, 2018—a decline of $2.57 per share or approximately 2.3% on high trading volume, and loss of $4.8 billion in market capitalization.

G. After the Flawed Clinical Trials and FDA Concerns Were Disclosed, Defendants Misrepresented iQOS Growth in Japan

106. Before the disclosure of the flawed clinical trials and FDA concerns, iQOS had been widely successful in Japan as a result of Philip Morris's representations that iQOS was significantly less harmful than conventional cigarettes. Japanese iQOS users were remarking that "the reason why iQOS' popularity does not decline" is that "the harmful substances are reduced by more than 90% compared to the traditional cigarettes (carcinogenic risk is greatly reduced) . . . . If you want to smoke but are concerned about health, changing to iQOS is a really good choice."

107. iQOS was released nationwide in Japan on April 18, 2016, with great fanfare. Indeed, one commentator noted on April 19, 2016: "Scientific demonstration results are published! What are iQOS's effects on health?", pointing to the following representations made by Philip Morris on its official website: "Scientific Evaluation of IQOS Based on International Standard" – "We tested 58 harmful substances that are produced by iQOS's steam and compared their level with the traditional cigarettes and they are reduced by about 90% on average."

108. Continuing this misleading marketing campaign, on October 14, 2016, Philip Morris issued a press release titled "Participated in the 51st Annual Meeting of the Japan Alcohol Addiction Medical Association, provided a lower risk alternative to smoking cigarette and held a discussion meeting on the topic of 'tobacco harm reduction.'" Philip Morris

presented the results of its scientific research on iQOS, including toxicity tests and clinical trials, which supposedly demonstrated reduction of smoking-related disease risks. In an interview after the results were presented, Defendant Lüdicke said, "To spread RRP, it is important not only to improve the technology but also to disseminate information at places like this kind of symposium and to make it recognized in the world. Furthermore, it is necessary to create a convenient environment for consumers to get it just like the regular cigarettes."

109. *Tokyo Economic News* reported on March 5, 2017 that iQOS rapidly gained market share in Japan because it "is considered 90% less harmful."

110. On October 19, 2017, Philip Morris announced its financial results for the three months ended September 30, 2017. During the Company's earnings call, held the same day, Defendant Olczak discussed a number of dynamics that purportedly put Philip Morris on track for a strong first quarter of 2018 in Japan. In particular, according to Olczak, iQOS device supply constraints that the Company was currently facing would be alleviated by the increased production from a second supplier. Historically, the Company had manufactured all iQOS devices at one manufacturing plant.

111. By adding a new Asia-based supplier of iQOS devices, Philip Morris would be able to build inventory levels of both devices and HeatSticks to meet the purportedly growing demand for iQOS in the crucial Japanese market. In addition, Philip Morris was in the process of transitioning from the shipment of HeatSticks by air freight to sea freight, which would enable the Company to provide an increased supply to the market. While showing the below slide as part of his presentation, Olczak stated, in pertinent part, as follows:

> Importantly, we are beginning to fully supply the Japanese market with HeatSticks and ***build normal inventory levels commensurate with the growth in demand***, a process that we expect to continue in the fourth quarter. As part of this effort, we began to process -- the process of shifting our HeatSticks shipments to

Japan from air freight to sea freight during the third quarter. ***However, we effectively remain supply-constrained in the market due to iQOS device capacity. This limitation should gradually ease over the coming months, in part due to the increasing contribution of devices from our second supplier. We expect to be able to fully supply the market with devices in early 2018 based on our current demand forecast***. . . .

112. Defendant Olczak reiterated that the Company would be free from supply constraints beginning in the first quarter, stating "Q1, I assume when the devices should be in the free supply and the HeatSticks will have an inventory and we'll continue to be in a full supply, we should start seeing the first quarter of operations result in a constraint on neither the device nor the HeatSticks."

113. In Japan, for the third quarter of 2017, the Company reported an 11.9% market share for HeatSticks, which represented an 8.4% year-over-year increase. According to the Company's February 13, 2018 Form 10-K, market share is calculated for Japan "as the total sales volume for heated tobacco units as a percentage of the total estimated sales volume for cigarettes

and heated tobacco units." Overall, Philip Morris shipped 8.3 billion HeatSticks to Japan in the third quarter.

114. During the question and answer portion of the earnings call, a Citigroup analyst pointed out the fact that while the Company was reporting a quarter-on-quarter increase in the Japanese market share for HeatSticks, that growth was actually slower in the third quarter of 2017 compared to the prior quarter – *i.e.*, 1.9% 3Q17 market share increase vs. 2.9% 2Q17 market share increase.

115. The Citigroup analyst asked Defendant Olczak if the slower growth was "entirely due to the fact that you have supply constraints on the devices? Or is it perhaps because you're now so large as you're growing market share is harder?" Olczak confirmed that it was the former, stating, *inter alia*, that he "***would put the highest weight to the device availability rather than our dynamic in the market***."

116. Analysts were encouraged by Defendants' representations that the Company would be able to fully supply the Japanese market in response to the "growth" in demand for iQOS, beginning in the first quarter of 2018. For example, a November 15, 2017 report by analysts at Wells Fargo stated, in pertinent part, as follows:

> We were pleased to hear that iQOS' strong success continues with solid market share gains across key markets, including Japan where iQOS' national share in is now at 13.3% share vs 11.9% in 3Q17. The brand's high consumer touch rate & ***strong word-of-mouth marketing in Japan has led to a growing set of loyal customers*** – many of whom seek to own multiple iQOS devices and pursue faster upgrades. PM currently estimates iQOS device ownership at roughly 1.5 devices per consumer (based on a total of ~4M iQOS consumers).
>
> While a welcome challenge, ***the increased demand continues to put pressure on device supply which, while starting to ease with the second manufacturer now online, will not likely get fully resolved until early 2018 given PM's current forecast for demand***. Other key updates: PM remains on track to (1) roll out iQOS to a total of up to 35 markets by year end (31 currently); (2) ***raise HeatStick inventory in Japan to levels that will be commensurate with strong demand by year end***; (3) continue to build iQOS awareness and product comprehension

among adult smokers in European countries where laws governing consumer communication are much stricter than they are in Asia.

117. Revelations about the FDA's refusal to approve Philip Morris's application to promote iQOS as a reduced-risk product began to enter the Japanese market, negatively impacting sales. On January 26, 2018, *The Wall Street Journal Japan* stated that the FDA Advisory Committee's denial of iQOS "was a hit on the industry. It disproves Philip Morris's advertising that iQOS causes less damage to health."

118. On or about January 29, 2018, the Japan Society for Tobacco Control ("JSTC") posted Emergent Warnings about "Heated Cigarettes" on its official website and attached a document titled *FDA Advisory Committee Determined That IQOS Is Not Safe*, which stated that the FDA's Tobacco Products Scientific Advisory Committee denied Philip Morris's claim that IQOS is less harmful than traditional cigarettes. The article also noted that the University of California San Francisco submitted 10 public comments supporting the FDA Scientific Advisory Committee's opinion that the claim that "exposure to harmful substances is reduced" leads to the misleading impression that "IQOS is less harmful," when in truth it cannot be said iQOS is safer than conventional cigarettes. JSTC said that other countries will also not be deceived by Philip Morris.

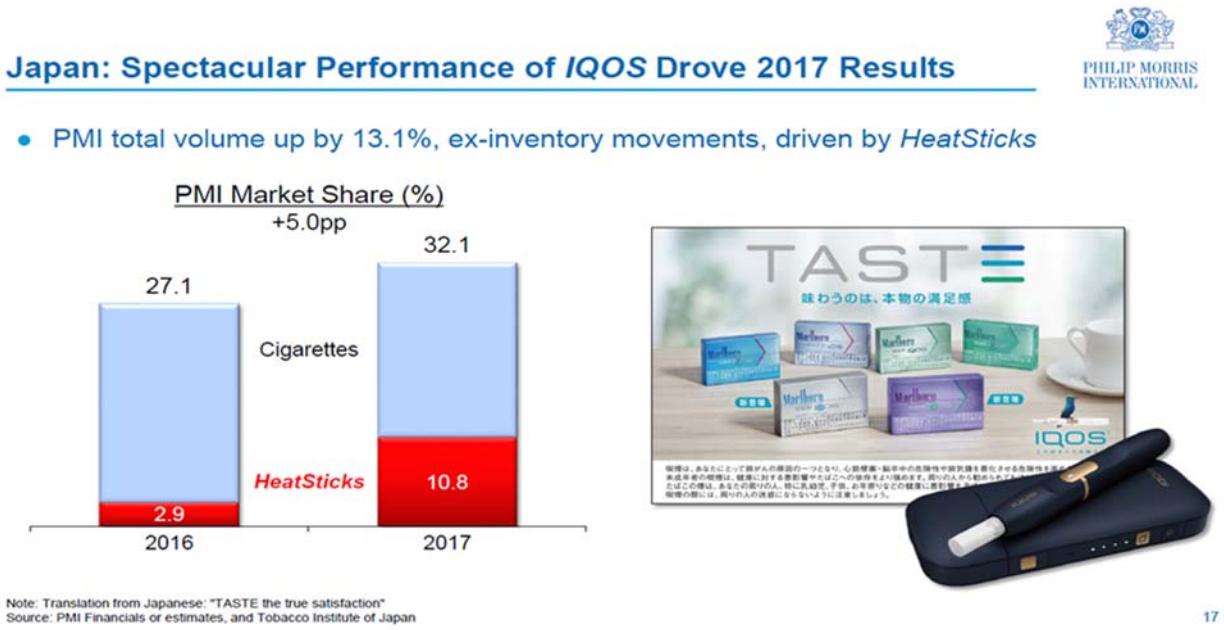
119. Despite these obvious market concerns about the health risks caused by iQOS, Philip Morris continued to misleadingly reassure investors that the "strong growth [in our heated tobacco unit[s]] continued in January [2018]," "[o]ur weekly offtake shares in Japan continued to grow in January, both nationally and in the prefectures where the heated tobacco category is the most mature for a competitive standpoint," and represented that demand for iQOS in Japan is "anticipated to further increase in the first quarter of 2018."

120. On February 8, 2018, Philip Morris announced its financial results for the fourth quarter and year ended December 31, 2017. The Company reported a strong fourth quarter, with year-over-year cigarette and heated tobacco unit shipment volumes increasing by 3.8% and net revenues, excluding excise taxes, increasing by 19%. Defendants also provided a 2018 full-year forecast that projected "[n]et revenue ***growth***, excluding excise taxes, of ***over*** 8.0%, excluding currency."

121. Heated Tobacco Unit (or HeatStick) shipping volume increased substantially in the fourth quarter for Philip Morris. The Company reported that it had shipped 15.7 billion HeatSticks, which represented a 60% increase from the prior quarter and a 325% year-over-year increase.

122. Philip Morris also announced that the market share for HeatSticks in Japan had increased during the fourth quarter to 13.9% – up from 11.9% in the prior quarter.

123. On the heels of the Company's strong fourth quarter in Japan, during Philip Morris's earnings call held the same day, Defendant Calantzopoulos stated that the Company's growth in Japan was the result of an "***increasing demand for HeatSticks, which we expect to grow further in the first quarter following a planned lifting of the restriction on iQOS device sales; the establishment of appropriate distributor inventory levels of heated tobacco units, given the current high dependence on a single manufacturing center. . . .***" While making these remarks, Calantzopoulos showed the following presentation slide:



124. Also during the call, when asked by a Goldman Sachs analyst about the Company's outlook for iQOS performance and Heatstick volume in Japan in 2018, Calantzopoulos responded that ***"we have our own projection for total market in Japan, including obviously HeatSticks. And there's nothing in the horizon that would affect -- that would cause any change in what happened in the previous years. . . ."***

125. Following these announcements, several analysts issued reports indicating their understanding that 2018 was going to be a banner year for iQOS, especially in Japan, now that capacity constraints were a thing of the past for Philip Morris. For example, a February 8, 2018, Wells Fargo report stated, in pertinent part:

> ***[H]uge momentum in iQOS*** with over 4.7M adult consumers fully switching to iQOS & capacity constraints no longer an issue (should silence market bears).
>
> * * *
>
> We believe 2018 will be a pivotal year as PM starts to ***unleash the full potential of iQOS*** now that capacity constraints are resolved.
>
> * * *

> ***iQOS' Stellar Performance Should Silence Even The Loudest Bears*** – iQOS' exceptional performance in Q4 was again broadbased, led by ***strong share gains in Japan (16.7% in the 3rd wk of Jan vs 16.2% in Dec & 14.7% in Oct)*** and an acceleration across other markets (including some of the more difficult ones such as Italy & Switzerland) as PM improves its commercial execution and ability to build consumer awareness & brand loyalty. ***Importantly, iQOS capacity issues are now in the rear view mirror and based on its strong run-rate, we expect iQOS HeatSticks to comprise ~9% of PM's total vol by year end, reaching ~13% by 2019.***

126. The next day, Morgan Stanley analysts also published a report expressing their belief that iQOS' positive performance was set to continue. Specifically, the report stated that "***Q4 results delivered arguably the strongest evidence yet of iQOS' increasing momentum***, which should be sustained by $600 MM in planned 2018 incremental spend (underlying EPS +7-10%)."

127. More than halfway through the first quarter, on February 21, 2018, Defendants raised the market's expectations for the Company's first quarter in Japan to new levels. On that date, Defendants Calantzopoulos, King and Olczak each spoke on behalf of Philip Morris at the Consumer Analyst Group of New York ("CAGNY") conference, giving lengthy presentations on the Company's performance.

128. While giving his remarks, Defendant Calantzopoulos reported that the Company was "progressing" on various initiatives "to accelerate growth" in heated tobacco unit sales and avowed that the Company was on an upward trajectory. He also pitched Philip Morris as a "***growth stock***," declaring that "8% plus currency-neutral ***net revenue growth is not just a 2017 or 2018 phenomenon***."

129. During his presentation, Defendant Olczak spoke at length about the current performance of iQOS in the Japanese market. While showing a slide titled "***IQOS: Growing National Market Shares***" Olczak stated that **"*[t]his growth trend continued in January of***

2018." The "growth trend" that Olczak presented for iQOS in Japan during January 2018 was a 16.3% national market share.

130. Olczak also showed a presentation slide with the percentage of "weekly offtake shares" for HeatSticks in the Fukuoka, Sendai, and Tokyo markets, as well as on a national level through January 28, 2018. According to Defendants' presentation materials, in Japan, "offtake share represents select C[onvenience]-Store sales volume for HeatSticks as a percentage of the total retail sales volume for cigarettes and heated tobacco units." Olczak declared that ***"[o]ur weekly offtake shares in Japan continued to grow in January, both nationally and in the prefectures where the heated tobacco category is the most mature from a competitive standpoint***."

131. With respect to the Company's performance in the city of Sendai, Olczak stated that "***our weekly offtake share growth in January drove further growth in our heated tobacco category share***. In fact, the category's growth was ***driven primarily by iQOS***."

132. Olczak also touted the supposed success the Company was experiencing in switching consumers from conventional cigarettes to heated tobacco products, including iQOS in Japan. Making no mention of the decreased demand in Japan in light of the FDA's rejection of Philip Morris's safety claims about iQOS and of any difficulties in trying to get older, more conservative smokers to switch to iQOS, Olczak insisted that ***"[o]ur strong share performances for iQOS continue to be underpinned by high iQOS switching across markets . . . [t]he most obvious example is Japan***, where there are now several heated tobacco products. Looking at IQOS switching, an estimated 68% of IQOS purchasers have switched exclusively to the heated tobacco category."

133. Olczak further declared that, in 2018, Philip Morris would "***go deeper with iQOS into our existing launch markets***."

134. In addition, Defendant King lauded the Company's RRP performance as "***remarkable***."

135. Analysts reacted favorably to Defendants' presentation at the CAGNY conference, which gave them the false impression that iQOS was on track for a very strong 1Q18 in Japan. For example, Morgan Stanley issued a report on February 21, 2018, stating, in pertinent part:

> PM delivered a 2018 CAGNY presentation which provided a detailed update of its commitment toward shifting both its own portfolio and the broader cigarette industry toward smoke-free products, led by the accelerating commercialization of iQOS across nearly 40 markets . . . . Recent data points for iQOS remain encouraging across a broad range of markets, ***with national market shares in more established markets rising further in January*** relative to Q4 (Japan 16.3%, vs. 13.9%; Korea 7.6%, vs. 5.5%; Romania 2.8%, vs. 1.9%; and Portugal 2.2%, vs. 1.5%). ***Additionally, the company's market share within the more competitively evolved market in Japan continues to trend positively***, including a sequential recovery to ~68% share in Sendai following recent competitor launches.

136. The same day, analysts from Wells Fargo issued a report summarizing their take-away from the Company's CAGNY presentation, which included, *inter alia*, that disappearing capacity constraints set Philip Morris up for a strong first quarter and their understanding from Defendants' presentation that iQOS conversion rates continued to be robust. The Wells Fargo report stated, in pertinent part, as follows:

> **PM: CAGNY Thoughts - iQOS Heats Up**
>
> Transformation to Smoke Free Future Well Underway
>
> **PM Demonstrates Significant Progress on iQOS & Readies to Unleash iQOS' "True" Potential As Capacity Constraints Fall Away – Reiterate Outperform**
> *– We came away from PM's CAGNY presentation today impressed and increm more positive on PM given the level of further detail on iQOS' oppty ahead esp.* as key barriers such as supply constraints fall away. . . .

* * *

> **iQOS Data Points All Very Encouraging** – PM Signals Deeper Focus on Current 38 Markets – ***We remain very encouraged by iQOS' progress as conversion rates remain strong (65-89%) & market shares cont. to rise in all 14 key markets*** (out of a total of 38 mkts today). Importantly, PM's priority is to "go deeper" into these existing markets and focus on accelerating growth there (we think to eventually achieve national scale) before further broadening its reach into new markets. We think this is prudent.

137. In reality, however, as would be revealed to investors: (i) demand for iQOS was significantly decreasing in Japan following the FDA's rejection of Philip Morris's safety claims about iQOS and revelations that iQOS is not less harmful than conventional cigarettes; and (ii) Philip Morris had already saturated the younger, easier-to-convert, iQOS user base and was struggling to get older, slower-to-change, cigarette smokers to switch to using the device in Japan – by far the Company's most important iQOS market.

138. Having inflated the share price with buoyant promises of stellar growth in Japan, Defendant Calantzopoulos dumped 49,000 shares of Philip Morris stock on the market, yielding proceeds of over $5 million.

H. Defendants Shocked The Market By Announcing That iQOS Sales Were Actually Slowing in Japan

139. On April 19, 2018, Philip Morris issued a press release announcing its first quarter 2018 financial results. In a shocking reversal from what Defendants had just relayed to the market at the CAGNY conference, Defendants revealed that growth in iQOS sales had actually slowed in the same Japanese markets that they had just glowingly portrayed. Specifically, Defendants announced that the Company was experiencing "***less-rapid-than-initially-projected growth in sales of devices to consumers in Japan in the first quarter, as we are now reaching more conservative adult smoker segments that may require, at least at first, slightly more time for adoption***."

140. For the first quarter, the Company reported 6.2 billion HeatStick shipments to Japan – nearly **7 billion** fewer HeatSticks than the Company shipped to that market in the prior quarter. Year-over-year, first quarter HeatStick shipment volumes to Japan increased by just 49%. This stood in stark contrast to the year-over-year increase in HeatStick shipments to Japan the Company reported in the prior three quarters of +274% (4Q17), +315% (3Q17), and +408% (2Q17). Overall, the Company reported first quarter HTU shipments of just 9.6 billion – down 39% from the fourth quarter and well below consensus estimates of 13.2 billion units.

141. Defendants also lowered the Company's previously-announced net revenue growth guidance to "***approximately*** 8.0%," notwithstanding Calantzopoulos' statement more than halfway through the first quarter that "8%-***plus*** currency-neutral net revenue growth is not just a 2017 or 2018 phenomenon."

142. The same day, on Philip Morris's earnings call, Defendant King stated that in Japan the Company sold fewer iQOS devices "due to still limited awareness of iQOS increased availability and, more importantly, to the fact that we are reaching, earlier in the year than we had anticipated, the more conservative consumers, especially the age 50-plus smoker segment, which represents approximately 40% of the total adult smoker population." He also stated that "we are now reaching different socioeconomic strata, with more conservative adult smokers who may have slightly slower patterns of adoption."

143. King further disclosed that in Japan the Company's market share growth had hit a "plateau," which Defendants were "anticipating" would be reached later in 2018. King revealed that Defendants were specifically aware that the Company was about to confront this issue head-on in Japan, stating that "***we knew the consumer dynamic that we had – close to saturating the***

early adopters and innovators" iQOS user groups in Japan. This dynamic had not been previously communicated to the market by Defendants.

144. In addition, Defendants announced that the Company had achieved a total Japanese tobacco market share for March of 15.6%, which implied that February – the same month during which Defendants touted a "growing" Japanese market share of 16.3% to investors at the CAGNY conference – had in fact been the ***worst month*** of the quarter for the Company in Japan.

145. During the question and answer portion of the call, Defendants were peppered with questions from analysts in light of what they had just reported at the CAGNY conference. For example, an analyst from Goldman Sachs asked Defendant King about the performance of iQOS in Japan, pointing out that "it sounded like at CAGNY, trends were pretty strong. I think you had January market share number for iQOS that was higher than the quarterly average."

146. In response, King made the startling revelation that the reported January market share numbers for Japan were actually **inflated** because of the timing of competitor shipments. He stated, in pertinent part, as follows:

> I think you mentioned the January share that probably you were looking at from CAGNY, which was given at 16.3%. We're focusing more on quarterly shares because there's always a bit of noise in those in-market shares. They're based on an exchange of data from the different companies. And sometimes, there's some inventory impacts as they ship to retail. If you look at December of last year, the in-market shares percent was 14.1%, so that -- ***it was probably a little understated versus -- due to some inventory increases from our competitors. And then 16.3% came in, in January probably a little overstated*** because of the reversing of that effect.

Defendants, however, made no mention of this issue during their extensive presentation at the CAGNY conference.

147. Defendant King also noted that the Company's outlook for total HeatStick volume in 2018 was set to be further reduced should the newly disclosed problems in Japan

continue. He stated that ***"if this situation in Japan persists, then our volume estimate for heated tobacco units will be more in the range of 55 billion to 60 billion versus the over 60 billion that we had called out before . . . ."***

148. Analysts were dismayed by the stunning news disclosed on April 19, 2018, that iQOS growth had slowed in Japan, despite being told the opposite more than halfway through the first quarter by Defendants. For example, analysts at Morgan Stanley issued a report on April 20, 2018 specifically noting the divergence between Defendants' statements at the CAGNY conference about iQOS performance in Japan and the Company's April 19 announcements. The report stated, in pertinent part, as follows:

> iQOS volumes of 9.6 Bn (vs. consensus 13.2 Bn) and Japan market share (15.8%, up from 13.9% in Q4 but below the 16.3% observed in January) unexpectedly slowed, where PM highlighted slower device sell-through as it attempts to expand its user base beyond "early adopters." ***To be fair, this followed a CAGNY presentation in February which came across as particularly bullish, a dynamic which only exacerbated the gap between Q1 expectations and actual results***.

149. Similarly, on April 24, 2018, Deutsche Bank analysts issued a report discussing the fact that these revelations flew in the face of what Defendants had just told investors during the CAGNY conference presentation on how well iQOS was performing in the first quarter in Japan. The Deutsche Bank report stated, in pertinent part, as follows:

> PMI has driven an aggressive IQOS focussed investor communication agenda in our view. ***As recently as February 21st (CAGNY) PMI described its RRP performance as "remarkable" and lauded IQOS's 16.3% Japan January share. In addition, PMI considered the impact of IQOS as ". . . unprecedented [when] compared to any tobacco regulatory measure" Punchy stuff. Of the 33 staples companies presenting at CAGNY our sense was investors perceived PMI's presentation as, or very close to, the most impressive of the week; PMI set expectations high. And then, only two months later, when announcing 1Q18 results PMI said they were highlighting some caution*** regarding ". . . less-rapid than- initially-projected growth in sales of devices to consumers in Japan in the first quarter, as we are now reaching more conservative adult smoker segments that may require, at least at first, slightly more time for adoption." Result? PMI share price –c17% in two days. Why? Because, in the market's view, credibility has been undermined by the ***disconnect between CAGNY and 1Q18 messaging.***

150. The Deutsche Bank report also discussed the Company's announcement that, in Japan, Philip Morris had saturated the younger, easier to convert, iQOS user base and was struggling to get older, slower-to-change, smokers to switch to iQOS. Deutsche Bank specifically noted that Defendants had not previously explained this issue to the market. The report stated, in pertinent part, as follows:

> In addition, PMI argues that this dynamic was common with any new product category, and especially one such as IQOS given its "*phenomenal speed of growth in Japan*". We get that. ***But while we argue PMI 'knows the rules' in terms of investor communication, these potential dynamics should have been given much greater prominence throughout the last two/three years of IQOS focused communication such that, when the dynamic emerged, investors were sufficiently prepared. They weren't***.

151. Further, the Deutsche Bank report pointed out the significant omission from Defendants' remarks at the CAGNY conference concerning iQOS market share levels in Japan and the new revelation that the January numbers Defendants had previously reported were actually inflated, stating as follows:

> PMI has noted that 16.3% IQOS share in Japan was inflated due to competitor shipment timings. Heavy shipments from competitors in December (off-set in December's share by PMI's inventory load) meant that January competitor shipments were 'light' inflating PMI's share. ***But . . . we weren't told that at CAGNY . . . which just adds to the problem***.

152. In response to this disappointing news, the price of Philip Morris common stock plummeted, falling from $101.44 per share on April 18, 2018, to close at $85.64 per share on April 19, 2018 – a decline of $15.80 per share, or approximately 15%, on high trading volume of more than 45 million shares trading, more than 10 times greater than the average daily trading volume during the Class Period.

153. After the Class Period, analysts continued to discuss the discrepancy between Defendants' comments at the CAGNY conference about current iQOS performance in Japan and the Company's reported 1Q18 results. For example, after Philip Morris issued its 2Q18 results,

analysts at Morgan Stanley issued a report on July 17, 2018, discussing how Defendants' representations at the CAGNY conference had given the market high expectations regarding iQOS market share in Japan. The report stated, in pertinent part:

> ***iQOS's slowing growth in Japan in 1Q18 created a crisis of confidence in the product's long-term success and contributed to the $29 bn deterioration in PM's market value since it reported 1Q18 earnings***. Taking a step back from iQOS's short-term performance, the product has been enormously successful in Japan, achieving ~16% market share within two years of its national launch, and revolutionized the Japanese cigarette industry. ***This initial rapid success in Japan, and PM's optimistic market share data provided at CAGNY, elevated the market's expectations for both the pace of HNB category growth and PM's market share growth rate***. ***From here, category growth in Japan should be more moderate as the product moves beyond initial adopters and increasing competition will result in users testing out various products.***

154. Similarly, following the Company's 2018 analyst day in Lausanne, Switzerland and the February 2019 CAGNY conference, Deutsche Bank analysts issued a report reflecting on the fallout from Defendants' CAGNY presentation a year earlier. The February 21, 2019 report stated:

> PMI was in the market's 'bad books' (to understate the severity of its position) and owed a debt of performance/***communication repayment*** to the many loyal *shareholders* that stuck with it. That process of 'redemption' commenced in earnest with September's CMD, see Letter from Lausanne. In Lausanne we heard the comment ". . . ***we need to under-promise and overdeliver" at least three times from CEO Calantzopoulos*** . . . We considered yesterday's CAGNY presentation as very measured…with the 'hype' of last year resigned to the 'lessons learned' dustbin. ***PMI owed the market a heavy 'debt' of rehabilitation following CAGNY 201[8]***.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

155. During the Class Period, Defendants made materially false and misleading statements concerning: (i) the Company's scientific studies; and (ii) sales growth in Japan.

A. Materially False and Misleading Statements Concerning the Company's Scientific Studies

1. The 2016 Statements

156. The Class Period begins on July 26, 2016. On that date, the Company filed a Form 10-Q for the quarter ended June 30, 2016 (the "2Q 2016 10-Q") with the SEC, which contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Calantzopoulos and Olczak, attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

157. The 2Q 2016 10-Q discussed iQOS and stated that the Company's "assessment approach and the studies conducted to date reflect the rigorous evidentiary package contemplated in the FDA's Draft Guidance for Modified Risk Tobacco Product Applications (2012)," stating:

> *Reduced-Risk Products*: . . . ***we are conducting extensive and rigorous scientific studies*** to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke and, ultimately, claims of reduced disease risk when compared to smoking cigarettes . . . ***We draw upon a team of world-class scientists*** . . . from a broad spectrum of scientific disciplines . . .

158. The statements referenced above in ¶157 that Philip Morris was conducting "extensive and rigorous scientific studies" and that it was using "world-class scientists" were materially false and misleading when made because the scientific studies did not comply with GCP and suffered from other deficiencies, as detailed above. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies, the durations of the studies were insufficient to provide meaningful data, and contaminated urine samples were used in some of the studies, invalidating their results.

159. Discussing Platform 1, which consisted of iQOS, the 2Q 2016 10-Q made the following representations:

> *Platform 1* uses a precisely controlled heating device that we are commercializing under the iQOS brand name . . . Six short-term clinical studies have been completed. ***The study results show a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constituents ("HPHCs") in adult consumers who switched to iQOS compared to adult consumers who continued to smoke cigarettes over a five-day period.*** The final report of a three-month clinical reduced-exposure study conducted in Japan has been issued, and the final report for a three-month clinical reduced-exposure study conducted in the U.S. will be issued shortly. ***In these studies, we observed reduction in all 15 biomarkers of exposure to corresponding HPHCs measured in those who switched to iQOS compared to those who continued to smoke cigarettes***. Furthermore, ***the reductions measured in those who switched to iQOS approached those that were observed in study participants who quit smoking for the duration of the study***.

160. The statements referenced above in ¶159 that the clinical studies showed "a substantial reduction" in HPHC over a five-day period approaching those study participants who quit smoking were materially false and misleading when made because they failed to disclose that:

(a) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators;

(b) the clinical studies suffered from other deficiencies such as the duration of the studies were insufficient to provide meaningful data; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

161. The 2Q 2016 10-Q made the following additional representations:

> In the United States of America, an established regulatory framework for assessing "Modified Risk Tobacco Products" exists under the jurisdiction of the Food and Drug Administration ("FDA") by virtue of a 2009 statute. We expect that future FDA actions are likely to influence the regulatory approach of other interested governments. ***Our assessment approach and the studies conducted to date reflect the rigorous evidentiary package contemplated in the FDA's Draft***

> ***Guidance for Modified Risk Tobacco Product Applications (2012)***. We have shared our approach and studies with the FDA's Center for Tobacco Products. We plan to submit a Modified Risk Tobacco Product Application as well as a Premarket Tobacco Application for Platform 1 in 2016.

162. The statements referenced above in ¶161 that Philip Morris's "assessment approach and the studies conducted to date reflect" the "rigorous evidentiary package" contemplated in the FDA's Draft Guidance for MRTPA were materially false and misleading when made because, for example, Philip Morris failed to provide robust scientific evidence to demonstrate that iQOS significantly reduces harm and the risk of tobacco-related disease. Moreover, Philip Morris was required to promptly disclose (but did not) that the clinical studies suffered from other deficiencies such as the duration of the studies being insufficient to provide meaningful data; and that some of the studies it conducted actually showed that iQOS contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

163. Further, the 2Q 2016 10-Q incorporated by reference the Risk Factors contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 (the "2015 10-K"), which contained the following risk disclosure:

> ***We may be unsuccessful in our attempts to introduce Reduced-Risk Products, and regulators may not permit reduced exposure or risk claims or the commercialization of these products.***
>
> We continue to seek ways to develop commercially viable new product technologies with the potential to reduce exposure to harmful constituents in smoke and individual risk and population harm, all in comparison to smoking cigarettes. Our goal is to develop products whose potential to reduce exposure, individual risk and population harm can be substantiated by rigorous scientific studies and that provide adult smokers the taste, sensory experience, nicotine delivery profile and ritual characteristics that are similar to those currently provided by cigarettes. We may not succeed in these efforts. If we do not succeed, but others do, we may be at a competitive disadvantage. Furthermore, we cannot predict whether regulators will permit the marketing of tobacco products or other nicotine-containing products with claims of reduced exposure or risk as compared with cigarettes. A prohibition on any such claims could significantly undermine the commercial viability of these products.

164. The risk factor referenced in ¶163 above was materially false and misleading when made, because it failed to disclose that the risk that Philip Morris would not obtain approval from the FDA to sell iQOS in the United States as a modified risk tobacco product was undermined by the fact that: (i) some of the iQOS clinical study results were invalid, as Philip Morris failed to comply with GCP and other generally accepted clinical study practices; and (ii) other scientific studies conducted by Philip Morris showed that iQOS contained compounds of toxicological concern in higher quantities than in conventional cigarettes, all of which were known to Defendants.

165. In August 2016, Philip Morris posted on its official website the following statements made by Defendant Calantzopoulos: "Scientific substantiation is fundamental. I think we are producing the best science you can produce in the field today." These statements were posted by Philip Morris on its official website in September, October, November, and December 2016.

166. The statements referenced above in ¶165 were materially false and misleading when made because Philip Morris was not "producing the best science you can produce in the field today." For example, Philip Morris's clinical trials failed to comply with GCP and the clinical studies suffered from other deficiencies such as the duration of the studies being insufficient to provide meaningful data, and the Company was withholding study results showing that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

167. On September 9, 2016, Philip Morris published a "poster" on its official website titled "Reduced exposure to harmful and potentially harmful constituents after 90 days of use of tobacco heating system 2.2 in Japan, which was prepared in part by Defendants Picavet and

Lüdicke. The poster discussed a clinical study that was conducted in Japan in 2013/2014, "designed to demonstrate sustained exposure reduction to selected HPHCs and to provide first insight on changes in clinical risk" between iQOS smokers and subjects who continued smoking and those who abstained from smoking. Defendants represented that the study was conducted "according to . . . GCP."

168. The statements referenced above in ¶167 were materially false and misleading when made because the study did not comply with GCP. For example, the investigator failed to obtain informed consent before collecting blood and/or urine samples, failed to obtain informed consent before screening procedures were applied, and was otherwise unqualified because, among other things, he did not have any knowledge about tobacco. Moreover, 20% of the total length of the study involved contaminated samples.

169. On September 29, 2016, during Philip Morris's Investor Day call with analysts and investors, Philip Morris's Chief Scientific Officer for Reduced-Risk Products, Defendant Peitsch, reiterated that the Company's approach follows FDA guidelines and made positive statements about the benefits of iQOS, stating:

> ***[W]e follow a multi-step research program that starts with aerosol characterization of the product, progresses to clinical studies, and tracks the impact of the product in the real world after its launch in the marketplace. At each step, we demonstrate a key component of the risk reduction potential of our Reduced-Risk Product before proceeding to the next step. Our assessment is aligned with the U.S. FDA's Draft Guidance for Modified Risk Tobacco Products . . .***
>
> ***In summary, the scientific research conducted across a range of studies demonstrates that IQOS has a wide array of benefits compared to smoking cigarettes. We have focused on the health effects of the product and its potential to reduce risk,*** on the product's environmental impact including odor and indoor air quality, and on short-term benefits such as oral hygiene. ***In each of these categories, we have substantiated important adult consumer messages.***

> ***Most importantly, the totality of the evidence generated to-date supports our conclusion that IQOS has the potential to reduce the risk of smoking-related diseases in adult smokers who switch to it completely.***

170. The statements referenced above in ¶169 that iQOS has many benefits compared to conventional cigarettes and that iQOS can reduce the risk of smoking-related diseases were materially false and misleading when made because they failed to disclose that:

(a) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators;

(b) the clinical studies suffered from other deficiencies such as the duration of the studies were insufficient to provide meaningful data; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

171. The statements referenced above in ¶170 that Philip Morris's risk assessment is aligned with the U.S. FDA's Draft Guidance was false and misleading when made for the reasons set forth in ¶162 above.

172. On the same day, the Company released Issue 1 of its Reduced-Risk Product Scientific Update report ("Scientific Report Issue I") which, according to the Company, "explains PMI's approach to product development and assessment, and provides an overview of the latest research, key peer-reviewed publications, and presentations at scientific conferences."

173. The Scientific Report Issue I contained the following statements by Defendant Peitsch:

> In order to demonstrate that switching to our RRPs results in a significant reduction in the risk of disease compared with cigarette smoking, ***we are following a rigorous scientific assessment program***. The program utilizes well-

> recognized practices of the pharmaceutical industry, as well as an innovative Systems Toxicology-based approach to risk assessment. ***Our program is in line with the draft guidance from the U.S. Food and Drug Administration for Modified-Risk Tobacco Products (MRTPs).***
>
> * * *
>
> To assess our RRPs ***we are taking a thorough and systematic stepwise approach which is inspired by the assessment methods used by the pharmaceutical industry and aligned with the U.S. Food and Drug Administration draft guidance for MRTP applications***. ***We conduct our research in accordance with international standards and practices, such as the internationally accepted Good Laboratory Practices (GLPs) and Good Clinical Practices (GCPs)***.

174. The statements referenced above in ¶173 that Philip Morris was following a "rigorous scientific" assessment program to demonstrate that RRPs pose less risk of disease and that the assessment was aligned with FDA's Draft Guidance and complied with GCP were materially false and misleading when made because the scientific studies did not comply with GCP. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies, the durations of the studies were insufficient to provide meaningful data, and contaminated urine samples were used in some of the studies, invalidating their results. Moreover, Philip Morris failed to provide robust scientific evidence to demonstrate that iQOS significantly reduces harm and the risk of tobacco-related disease. Additionally, Philip Morris was required to promptly disclose (but did not) that some of the studies it conducted showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

175. Additionally, the Scientific Report Issue 1 represented the following about the clinical trials it conducted over a three-month period to determine whether using iQOS reduces exposure to HPHCs:

> Reduced exposure studies are designed to help us understand the extent to which adult smokers who switch from cigarettes to our Electrically Heated Tobacco Product (EHTP) reduce their exposure to measured HPHCs. We compared these

> levels of exposure to those measured in smokers who continued to use cigarettes and those who quit smoking for the duration of the study, the "gold standard" for risk reduction.
>
> These studies were carried out over three months, and each involved 160 healthy adult smokers who were split into three groups: one group of 40 who continued smoking; another group of 40 who were asked to stop smoking for the duration of the study; and a final group of 80 smokers who switched to EHTP. The first five days of the study were spent in the clinic, and thereafter participants went home and were followed up at day 30, 60 and 90. We measured biomarkers of exposure to HPHCs, the substances the body generates when exposed to chemicals found in cigarette smoke.
>
> . . . ***These studies, like our entire clinical program, were conducted according to internally recognized Good Clinical Practices.***

176. The statements referenced above in ¶175 that Philip Morris's clinical studies of iQOS "were conducted according" to GCP were materially false and misleading when made because, in reality, they did not comply with GCP. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies. Moreover, the data reported by Philip Morris was not credible as it did not support the Company's claim that using iQOS resulted in less risk of harm or disease than smoking conventional cigarettes.

177. On October 8, 2016, Defendant Picavet and another Philip Morris employee presented the Company's strategy and clinical trial results at the 51st Annual Meeting of the Japanese Medical Society of Alcohol and Addiction Studies ("JMSAAS"). Philip Morris posted that presentation on the Company's official website on or around November 26, 2016, and made the following representations about the presentation:

> PMI's Science's assessment strategy is unique in its completeness and transparency. The[] [clinical] studies show that the toxicological profile of THS2.2 in the laboratory is almost indistinguishable from conditions where no cigarette is present . . . Harmful and potentially harmful compounds were reduced in THS2.2 aerosol by up to 96% compared to cigarettes and switching to THS2.2 in a clinical setting approached levels similar to cessation in terms of reduced exposure to these compounds.

> The totality of evidence to date regarding the potential harm reduction effects of THS2.2 are [sic] very encouraging both in terms of individual risk reduction and at a population level.

178. The statements referenced above in ¶177 that Philip Morris's scientific risk assessment strategy "is unique in its completeness and transparency," that the toxicological profile of iQOS is "almost indistinguishable from conditions where no cigarette is present," and that HPHC are reduced by up to 96% in iQOS were materially false and misleading when made because they failed to disclose that:

(a) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators;

(b) the clinical studies suffered from other deficiencies such as the duration of the studies were insufficient to provide meaningful data; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

179. Picavet's presentation represented that, on average, there were around 90-95% reductions in the formation of HPHCs for THS2.2 compared to conventional cigarettes and around 90-98% reductions in toxicity compared to levels measured for the 3R4F reference cigarette.[9]

180. The statements referenced above in ¶179 that iQOS contained 90-95% less HPHCs then conventional cigarettes and 90-98% less toxicity were materially false and misleading when made because they failed to disclose that:

[9] 3R4F refers to the reference cigarette developed by the University of Kentucky, serving as an international standard for research purposes.

(a) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators;

(b) the clinical studies suffered from other deficiencies such as the duration of the studies were insufficient to provide meaningful data; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

181. Picavet also presented results from pharmacokinetic studies conducted in Japan, representing the following:

> The reduction in levels of Biomarker of Exposure approaches levels observed on smoking cessation in Japan.
>
> * * *
>
> Levels of exposure to harmful and potentially harmful chemicals when smokers switch to THS2.2 approach the levels observed in those who quit smoking during the study.
>
> * * *
>
> Laboratory models show reduced activity in cellular mechanisms of disease. THS2.2 aerosol is over 10 times less active than reference cigarette smoke in key mechanisms leading to atherosclerotic plaque formation and endothelial cell dysfunction, which are important in cardiovascular disease development.
>
> * * *
>
> Clinical studies indicate favorable changes in clinical risk endpoints. These studies measured the levels of 5 clinical risk markers closely associated with cardiovascular disease. Measurements of these markers in smokers who switched to THS2.2 showed that the majority of beneficial effects that were seen in the smoking cessation arm were preserved.

182. The statements referenced above in ¶181 that exposure to HPHC is reduced to levels approaching smoking cessation when using iQOS, and that scientific studies show reduced

risks of disease were materially false and misleading when made because they failed to disclose that:

(a) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators;

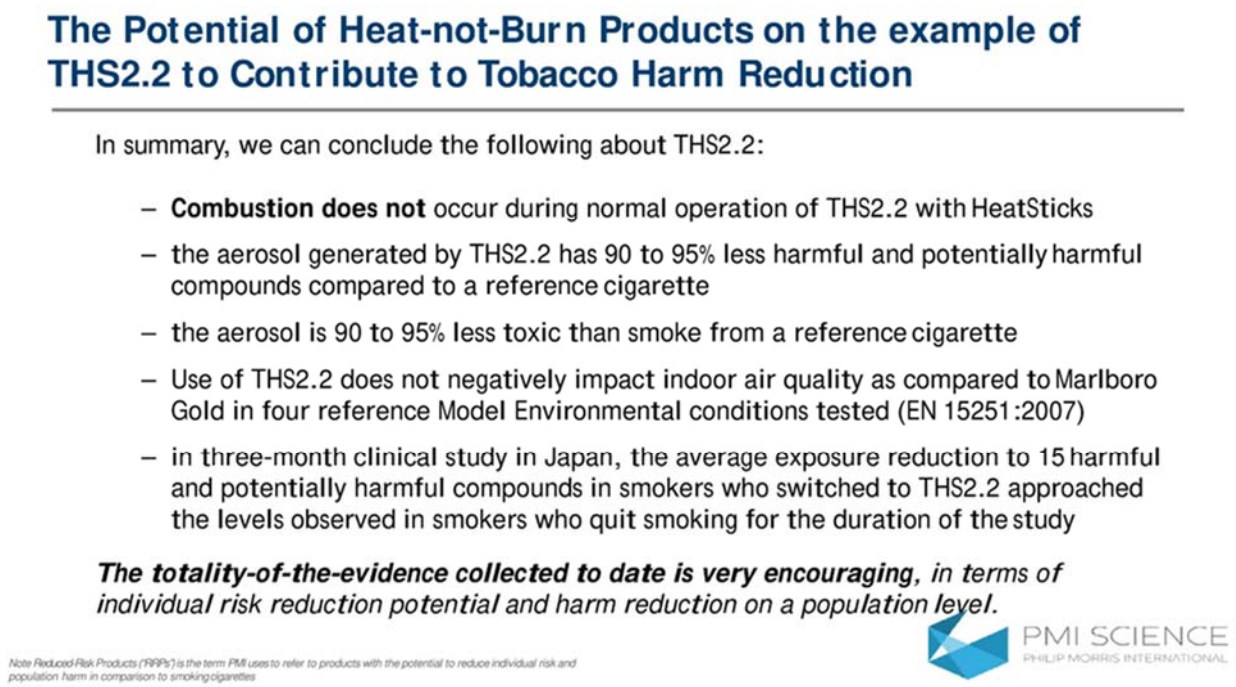
(b) the clinical studies suffered from other deficiencies such as the duration of the studies were insufficient to provide meaningful data; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

183. Picavet also represented that the scientific studies Philip Morris was conducting on iQOS were "extensive" and "rigorous."

184. The statements referenced above in ¶183 were materially false and misleading when made because the studies failed to comply with GCP and failed to follow FDA Draft Guidance for MRTPA.

185. Picavet provided the following "conclusions" about THS2.2:



186. The statements referenced above in ¶185 that iQOS' aerosol has 90-95% less HPHC compared to a reference cigarette, that aerosol is 90-95% less toxic than the smoke of a reference cigarette, that in one clinical study in Japan, exposure to 15 HPHCs was reduced to a level akin to smoke cessation, and that the totality of the evidence points to risk and harm reduction were materially false and misleading when made because they failed to disclose that:

(a) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators;

(b) the clinical studies suffered from other deficiencies such as the duration of the studies were insufficient to provide meaningful data; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

187. On October 25, 2016, the Company filed a Form 10-Q for the quarter ended September 30, 2016 (the "3Q 2016 10-Q") with the SEC, which contained signed certifications pursuant to SOX by Defendants Calantzopoulos and Olczak, attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

188. The 3Q 2016 10-Q discussed iQOS and stated that the Company's "assessment approach and the studies conducted to date reflect the rigorous evidentiary package contemplated in the FDA's Draft Guidance for Modified Risk Tobacco Product Applications (2012)," stating in pertinent part:

> *Reduced-Risk Products*: . . . To date, almost one million adult smokers have converted to our iQOS product described below. Our RRPs are in various stages of development and commercialization, and we are conducting extensive and rigorous scientific studies to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke and, ultimately, claims of reduced disease risk when compared to smoking cigarettes. . . . We draw upon a team of world-class scientists . . . from a broad spectrum of scientific disciplines . . .

189. The statements referenced above in ¶188 were materially false and misleading when made for the reasons set forth in ¶158 above.

190. The 3Q 2016 10-Q disclosed the following with respect to the Company's short-term clinical trials results:

> *Platform 1* uses a precisely controlled heating device that we are commercializing under the iQOS brand name . . . Six short-term clinical studies have been completed. ***The study results show a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constituents ("HPHCs") in adult consumers who switched to iQOS compared to adult consumers who continued to smoke cigarettes over a five-day period.*** The final reports of the three-month clinical reduced-exposure studies conducted in Japan and the U.S. have been issued. ***In these studies, we observed reduction in all 15 biomarkers of exposure to corresponding HPHCs measured in those who switched to iQOS compared to those who continued to smoke cigarettes. Furthermore, the reductions measured in those who switched to iQOS***

approached those that were observed in study participants who quit smoking for the duration of the study.

191. The statements referenced above in ¶190 were materially false and misleading when made for the reasons set forth in ¶160 above.

192. The 3Q 2016 10-Q made the following additions representations:

> In the United States of America, an established regulatory framework for assessing "Modified Risk Tobacco Products" exists under the jurisdiction of the Food and Drug Administration ("FDA"). We expect that future FDA actions are likely to influence the regulatory approach of other interested governments. ***Our assessment approach and the studies conducted to date reflect the rigorous evidentiary package contemplated in the FDA's Draft Guidance for Modified Risk Tobacco Product Applications (2012).***

193. The statements referenced above in ¶192 were materially false and misleading when made for the reasons set forth in ¶161 above.

194. The 3Q 2016 10-Q incorporated the same risk factors as the 2Q 2016 10-Q which were materially false and misleading for the reasons discussed in ¶164.

2. The 2017 Statements

195. In January 2017, Philip Morris posted on its official website the following statements made by Defendant Calantzopoulos: "Scientific substantiation is fundamental. I think we are producing the best science you can produce in the field today." These statements were posted by Philip Morris on its official website also in February, March, April, May, June, July, August, September, October, November, and December 2017.

196. The statements referenced above in ¶195 were materially false and misleading when made for the reasons set forth in ¶166 above.

197. On February 14, 2017, the Company filed a Form 10-K for the fiscal year ended December 31, 2016 (the "2016 10-K") with the SEC, which contained SOX signed certifications by Defendants Calantzopoulos and Olczak, attesting to the accuracy of financial reporting, the

disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

198. The 2016 10-K stated the following regarding IQOS:

> *Reduced-Risk Products* . . . We conduct rigorous scientific assessment of our RRP platforms to establish that they reduce exposure to harmful and potentially harmful constituents in smoke and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking. We draw upon a team of expert scientists . . . from a broad spectrum of scientific disciplines and our extensive learnings of consumer preferences to develop and assess our RRPs.

199. The statements referenced above in ¶198 were materially false and misleading when made for the reasons set forth in ¶158 above.

200. The 2016 10-K made the following additional representations with respect to the clinical studies conducted on iQOS:

> Platform 1 uses a precisely controlled heating device that we are commercializing under the IQOS brand name . . . ***Eight clinical studies have been completed (including two with the duration of three months). The study results show a substantial reduction in relevant biomarkers of exposure to harmful or potentially harmful constituents ("HPHCs") in those adult smokers who switched to IQOS compared to those who continued to smoke cigarettes for the duration of the study. The reductions measured in those who switched to IQOS approached those that were observed in study participants who quit smoking for the duration of the study***. While these reduced exposure clinical studies were primarily designed to focus on biomarkers of exposure, in our three-month studies, ***we also measured six clinical risk markers. These clinical risk markers are associated with disease mechanisms known to be affected by smoking and to reverse upon cessation. The results are generally consistent with the expected direction of change and indicate that switching completely to IQOS led to an overall improvement of clinical risk markers affected by smoking after only three months***.

201. The statements referenced above in ¶200 were materially false and misleading when made for the reasons set forth in ¶160 above.

202. In addition, the 2016 10-K contained the following risk disclosure:

> ***We may be unsuccessful in our attempts to introduce Reduced-Risk Products, and regulators may not permit the commercialization of these products or health-related claims.***
>
> Our key strategic priorities are: to develop and commercialize products that present less risk of harm to adult smokers who switch to those products versus continued smoking; and to convince current adult smokers who would otherwise continue to smoke to switch to those RRPs. For our efforts to be successful, we must: develop RRPs that such adult smokers find acceptable alternatives to smoking; conduct rigorous scientific studies to substantiate that they reduce exposure to harmful and potentially harmful constituents in smoke and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking; and effectively advocate for the development of science-based regulatory frameworks for the development and commercialization of RRPs, including communication of scientifically substantiated information to enable adult consumers to make better health choices. We might not succeed in our efforts. If we do not succeed, but others do, we may be at a competitive disadvantage. Furthermore, we cannot predict whether regulators will permit the sale and/or marketing of RRPs with health-related claims. Such restrictions could limit the success of our RRPs.

203. The risk factor referenced in ¶202 above was materially false and misleading when made, because it failed to disclose that the risk that Philip Morris would not obtain approval from the FDA to sell iQOS in the United States as a modified risk tobacco product was undermined by the fact that: (i) some of the iQOS clinical study results were invalid, as Philip Morris failed to comply with GCP and other generally accepted clinical study practices; and (ii) other scientific studies conducted by Philip Morris showed that iQOS contained compounds of toxicological concern in higher quantities than in conventional cigarettes, all of which were known to Defendants.

204. On March 27, 2017, Philip Morris issued a press release titled "Latest clinical research confirms that IQOS reduces smoker exposure to select harmful chemicals as compared to cigarette smoke." The Company represented that the "[s]tudies conducted to date clearly indicate that IQOS is likely to present less risk of harm compared to smoking." It also represented that smokers who switched to iQOS:

- Reduced their exposure to 15 harmful chemicals to levels that approached those of smokers who quit smoking;

- Showed improvements in measured health indicators specific to smoking-related diseases, such as lung and heart disease.

205. The statements referenced above in ¶204 were materially false and misleading when made because:

(a) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced; and

(b) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

206. The press release also quoted the following statements made by Defendant Lüdicke:

> This study is an important step to confirm that while IQOS is not risk-free, it is a better choice for the millions of smokers who do not quit. It clearly indicates that smokers who switch to IQOS reduce their exposure to harmful compounds to levels that approach those of smokers who quit smoking. The study also clearly indicates areas of significant risk reduction which we are currently confirming through a longer term study.

207. The statements referenced above in ¶206 were materially false and misleading when made because:

(a) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced; and

(b) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

208. On April 27, 2017, the Company filed a Form 10-Q for the quarter ended March 31, 2017 (the "1Q 2017 10-Q") with the SEC, which contained signed certifications pursuant to SOX by Defendants Calantzopoulos and Olczak, attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

209. The 1Q 2017 10-Q stated the following regarding iQOS:

> ***We conduct rigorous scientific assessments of our RRP platforms*** to substantiate that they reduce exposure to HPHCs and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking. ***We draw upon a team of expert scientists*** . . . from a broad spectrum of scientific disciplines and our extensive learnings of adult consumer preferences to develop and assess our RRPs.

210. The statements referenced above in ¶209 were materially false and misleading when made for the reasons set forth in ¶158 above.

211. Discussing Platform 1, the 1Q 2017 10-Q represented the following facts:

> Platform 1 uses a precisely controlled heating device that we are commercializing under the IQOS brand name . . . ***Eight clinical studies have been completed (including two with an exposure period of three months). The study results show a substantial reduction in relevant biomarkers of exposure to HPHCs in those adult smokers who switched completely to IQOS compared to those who continued to smoke cigarettes for the duration of the study. These reductions approached those that were observed in study participants who quit smoking for the duration of the study***. While these reduced exposure clinical studies were primarily designed to focus on biomarkers of exposure, ***we also measured six clinical risk markers. These clinical risk markers are associated with disease mechanisms known to be affected by smoking and to reverse upon cessation. The results are generally consistent with the expected direction of change that is observed upon quitting and indicate that switching completely to IQOS led to an overall improvement of clinical risk markers affected by smoking after only three months***.

212. The statements referenced above in ¶211 were materially false and misleading when made for the reasons set forth in ¶160 above.

213. The 1Q 2017 10-Q incorporated the risk factor disclosures identified in Philip Morris's 2016 Form 10-K, which were materially false and misleading for the reasons discussed in ¶203.

214. In May 2017, Philip Morris published Issue 2 of its Scientific Update for Smoke-Free Products ("Scientific Update Issue 2"). There, the Company made the following representations:

> [A]t the operating temperatures of our heated tobacco products, the harmful chemicals found in tobacco smoke are reduced on average by 90-95%. Furthermore, two specific markers of combustion, namely carbon monoxide and nitrogen oxides, are reduced by approximately 98%.

215. The statements referenced above in ¶214 that the harmful chemicals found in conventional cigarettes are reduced by 90-95% in iQOS and that carbon monoxide and nitrogen oxide are reduced by approximately 98% were materially false and misleading when made because they failed to disclose that:

(a) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes; and

(b) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced.

216. In Scientific Update Issue 2, the Company also represented the following with respect to its assessment of iQOS:

> Our studies are very advanced and point in the direction of risk reduction. We have already completed numerous laboratory studies and eight clinical studies.

217. The statements referenced above in ¶216 that Philip Morris's studies were "very advanced" and "point in the direction of risk reduction" were materially false and misleading when made because the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, that the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced.

218. In Scientific Update 2, Philip Morris also disclosed the following results regarding one of its two three-month clinical studies, which was conducted in Japan:

> Results showed that smokers who switched to EHTP:
>
> • Reduced their exposure to 15 harmful chemicals to levels that approached those observed in smokers who abstained from smoking for the duration of the study.
>
> • Showed improvements in clinical risk markers related to lung and heart disease. In all cases, the clinical risk markers improved in the same direction as seen in smokers who abstained from smoking. . . .
>
> * * *
>
> The research was conducted in line with internationally respected guidelines for clinical trials, such as Good Clinical Practice.

219. The statements referenced above in ¶218 that exposure to 15 harmful chemicals was reduced to a level akin to smoke cessation and that risk markers related to lung and heart disease were similarly reduced in iQOS were materially false and misleading when made because they failed to disclose that:

(a) other scientific studies conducted by Philip Morris showed that iQOS actually contained compounds of certain toxicological concern in higher quantities than in conventional cigarettes; and

(b) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced.

220. The statement referenced above in ¶219 that Philip Morris's research was conducted in line with GCP was false and misleading when made for the reasons set forth in ¶168 above.

221. The discussion about the research results in Scientific Update 2 continued:

> PMI published a series of nine publications describing our smoke-free assessment program and sharing results from the non-clinical assessment and initial clinical studies of EHTP, referred to in the papers as THS2.2. ***This includes studies demonstrating that the lack of combustion greatly reduces the formation of harmful and potentially harmful constituents (HPHCs) compared with cigarette smoke. In vitro and in vivo assessments of the aerosol reveal reduced toxicity and no new hazards. Additional mechanistic endpoints, measured as part of the in vivo studies, are described and confirm a reduced impact on smoking-related disease networks. A clinical study described in one of the papers confirmed the reduced exposure to HPHCs in smokers switching to EHTP***. This research forms the core of our application to the U.S. FDA for EHTP as an MRTP.

222. The statements referenced in ¶221 above that iQOS's aerosol contains greatly reduced HPHCs, reduced toxicity and no new hazards, and presents less risk of diseases were materially false and misleading when made because:

(a) Other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes; and

(b) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced.

223. On June 21, 2017, *Time Online* published an interview with Defendant Calantzopoulos, during which he represented that iQOS is less harmful than cigarettes:

> Q: What's new about the HeatSticks?
>
> A: They contain real tobacco and are similar in taste to cigarettes. But because they do not burn, ***the concentration of harmful chemicals***

> ***decreases by an average of 90 percent relative to the smoke of a cigarette . . .***
>
> * * *
>
> A: . . . But they are most likely significantly less harmful to health than cigarettes.
>
> Q: According to the World Health Organization (WHO), tobacco kills seven million people every year. What would your death record look like for heat sticks?
>
> A. ***. . . I believe Heat Sticks also reduce the number of illness-related illnesses. Our studies provide strong evidence for this.***
>
> Q: With its studies, Philip Morris has lied to the public for decades. It was said: tobacco does not harm unborn children, passive smoking is harmless, nicotine does not make one dependent. Why should we believe you this time? . . .
>
> A: I do not ask you to trust me, I ask you to ***check our data! The aerosol of the heat sticks is analyzed quickly, in comparison with cigarette smoke you immediately recognize the decline of dangerous substances.*** . .

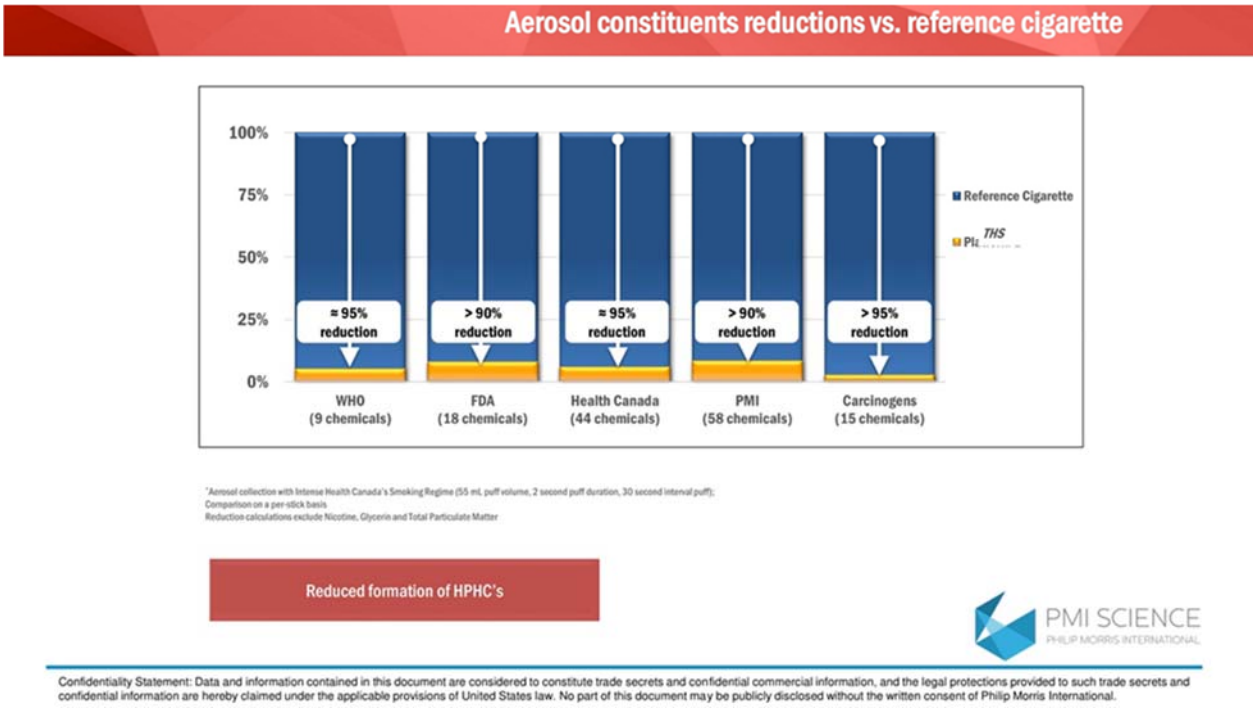
224. The statements referenced in ¶223 above that harmful chemicals in iQOS decreased by 90%, that iQOS 's "significantly less harmful to health than cigarettes," that Philip Morris's "studies provide strong evidence," that using iQOS also "reduce[s] the number" of diseases, and that with iQOS "you immediately recognize the decline of dangerous substances" were materially false and misleading when made because:

(a) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes; and

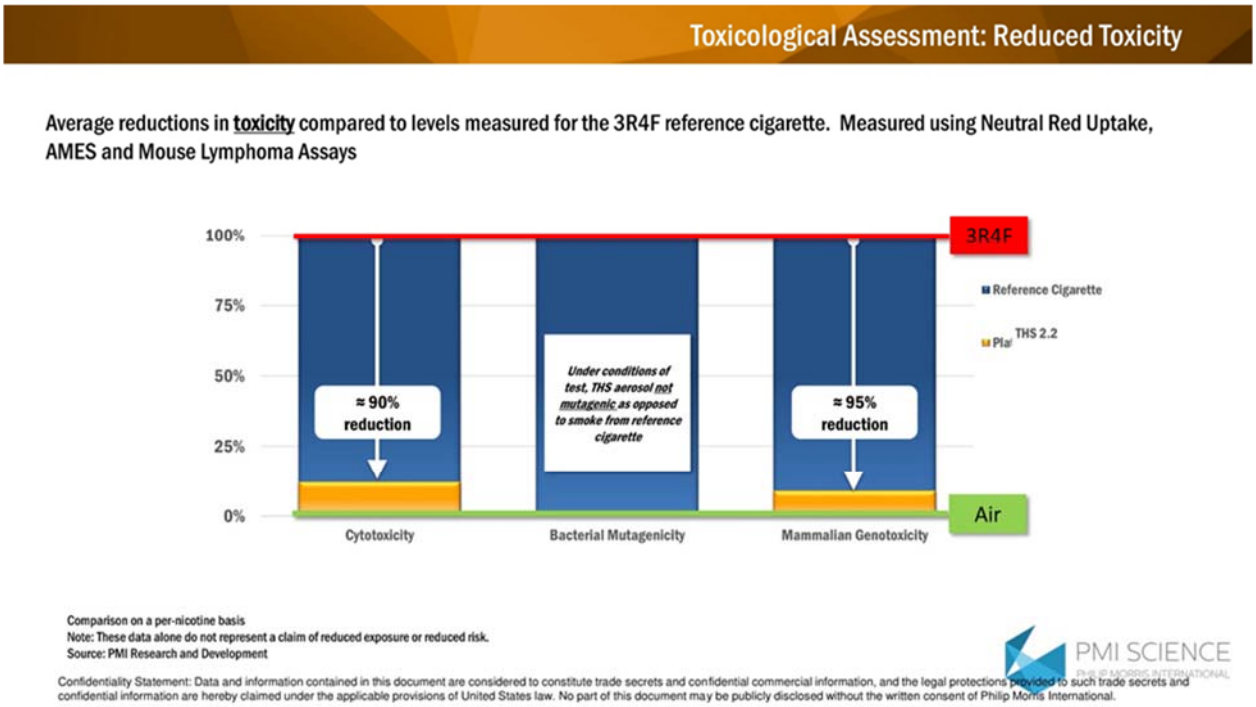
(b) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced.

225. On July 3, 2017, Patrick Picavet and another PMI employee presented the Summary of Results on the Tobacco Heating System at the NAAMA's [National Arab American Medical Association] 30th International Medical Convention. Philip Morris posted that presentation on the Company's official website on or around that time. In the presentation, Picavet represented that because Philip Morris's iQOS products "do not burn tobacco, *they produce far lower quantities of harmful and potentially harmful compounds than found in cigarette smoke*."

226. Picavet provided a graph depicting over 90% reductions in aerosol chemicals in iQOS over reference cigarettes:



227. Picavet also represented that, on average, there was a 90%-95% reduction in toxicity for iQOS compared to levels measured for the 3R4F reference cigarette:



228. Picavet also presented results from two 90-day exposure clinical studies, in Japan and the U.S., representing that the studies showed a "[r]eduction of 15 biomarkers of exposure in both studies."

229. The statements referenced in ¶¶225-28 above that in iQOS, HPHCs are reduced significantly, *i.e.*, by 90% and that toxicity is reduced on average by 90-95%, and that certain studies showed a reduction of 15 biomarkers of exposure were materially false and misleading when made because they failed to disclose that:

(a) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes; and

(b) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced.

230. On July 27, 2017, the Company filed a Form 10-Q for the quarter ended June 30, 2017 (the "2Q 2017 10-Q") with the SEC, which contained signed certifications pursuant to SOX by Defendants Calantzopoulos and Olczak, attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

231. The 2Q 2017 10-Q stated the following regarding iQOS:

> ***We conduct rigorous scientific assessments of our RRP platforms*** to substantiate that they reduce exposure to HPHCs and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking. ***We draw upon a team of expert scientists*** . . . from a broad spectrum of scientific disciplines and our extensive learnings of adult consumer preferences to develop and assess our RRPs.

232. The statements referenced above in ¶231 were materially false and misleading when made for the reasons set forth in ¶158 above.

233. Discussing Platform 1, the 2Q 2017 10-Q represented the following facts:

> Platform 1 uses a precisely controlled heating device that we are commercializing under the IQOS brand name . . . ***Eight clinical studies have been completed (including two with an exposure period of three months). The study results show a substantial reduction in relevant biomarkers of exposure to HPHCs in those adult smokers who switched to IQOS compared to those who continued to smoke cigarettes for the duration of the study. These reductions approached those observed in study participants who quit smoking for the duration of the study.*** While these reduced exposure clinical studies were primarily designed to focus on biomarkers of exposure, ***we also measured six clinical risk markers. Clinical risk markers are those that are associated with disease mechanisms known to be affected by smoking and to reverse upon cessation. The results are generally consistent with the expected direction of change that is observed upon quitting smoking and indicate that switching to IQOS led to an overall improvement of clinical risk markers affected by smoking after only three months***.

234. The statements referenced above in ¶233 were materially false and misleading when made for the reasons set forth in ¶160 above.

235. The 2Q 2017 10-Q incorporated the risk factor disclosures identified in Philip Morris's 2016 Form 10-K, which were materially false and misleading for the reasons discussed in ¶203.

236. On September 12, 2017, Philip Morris issued its 2016 Sustainability Report ("2016 Sustainability Report"), which it posted on the Company's official website. The report contained the following statements regarding the company's scientific assessment of iQOS:

> Our scientific assessment programs align with leading pharmaceutical industry standards and guidance issued by the US Food and Drug Administration's (FDA) Center for Tobacco Products. ***Our research includes laboratory and clinical studies based on internationally accepted Good Laboratory Practices and Good Clinical Practices***.
>
> * * *
>
> We follow a ***thorough and systematic approach*** to smoke-free product development and assessment, including clinical . . . studies to assess individual risk and population harm.
>
> * * *
>
> We conduct clinical studies with adult smokers according to the principles of Good Clinical Practice.

237. The statements referenced in ¶236 above that Philip Morris's scientific, "thorough and systematic" assessment programs aligned with the FDA guidance, and that its laboratory and clinical studies assessing risks and harm complied with GCP were materially false and misleading when made because the scientific studies did not comply with GCP and suffered from other deficiencies. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies, the durations of the studies were insufficient to provide meaningful data, and contaminated urine samples were used in some of the studies, invalidating their results. Philip Morris failed to provide robust scientific evidence to demonstrate that iQOS significantly reduces harm and the risk of tobacco-related disease.

Moreover, Philip Morris was required to promptly disclose (but did not) that some of the studies it conducted showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

238. The 2016 Sustainability Report also disclosed the following "findings" regarding the benefits of iQOS over conventional cigarettes:

> ***Findings to date show that switching completely to iQOS is likely to present less risk of harm than continued smoking.*** Specifically, the results show that:
>
> -IQOS does not generate combustion or smoke;
>
> -***IQOS vapor contains on average 90-95% lower levels of toxicants*** compared to the smoke from a reference cigarette designed for scientific research, with nicotine at similar levels to cigarette smoke;
>
> -Laboratory studies conducted in animal models of disease confirm that these lower levels of toxicants result in IQOS vapor being significantly less toxic than cigarette smoke;
>
> -Laboratory studies confirm that switching to IQOS, conducted in animal model of diseases, led to a reduction in key smoking-related diseases and their associated mechanisms. These reductions approached those observed in the cessation group; [and]
>
> -***Clinical studies conducted to date confirm the results of our laboratory studies. Smokers who switched completely to IQOS in two one-week and two three-month clinical studies significantly reduced their exposure to 15 toxicants***. These reductions approached levels observed in the cessation groups.
>
> ***These results give us confidence that switching fully to IQOS is likely to present less risk of harm than continuing to smoke*** . . . On this basis, in December 2016 we submitted evidence to the US FDA in the form of an application for IQOS as a modified risk tobacco product (MRTP)—the first ever for a heated tobacco product.

239. The statements referenced in ¶238 that iQOS contains 90-95% less toxicants than conventional cigarettes, that studies show lower levels of toxicants and a reduction in diseases approaching those of smoking cessation, and that these results "give us confidence that switching

fully to IQOS is likely to present less risk of harm than continuing to smoke" were materially false and misleading when made because Defendants failed to disclose that:

(a) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced;

(b) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

240. On October 2, 2017, Philip Morris posted on its official website a report entitled "The Science behind the Tobacco Heating System," a summary of published scientific articles. The report was written by, among others, Defendants Peitsch and Lüdicke. In the report's preamble, Defendant Peitsh stated that "[i]n order to demonstrate that switching to our RRP results in a significant reduction in the risk of disease compared with cigarette smoking, ***we are following a rigorous scientific assessment program***" that is "in line with the draft guidance from the U.S. Food and Drug Administration (FDA) for Modified-Risk Tobacco Products (MRTPs)." The report represented that Philip Morris's clinical trials were "conducted according to the International Conference on Harmonization (ICH) guidelines for Good Clinical Practice (GCP), Declaration of Helsinki, and local requirements."

241. The statements referenced in ¶240 above that, in order to demonstrate that switching to iQOS results in a significant reduction in the risk of disease, the Company is employing a "rigorous assessment program" that complies with the FDA Draft Guidance for

MRTPs and that the Company's clinical trials follow GCP were materially false and misleading when made because the clinical studies did not comply with GCP. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies, the durations of the studies were insufficient to provide meaningful data, and contaminated urine samples were used in some of the studies, invalidating their results. Philip Morris failed to provide robust scientific evidence to demonstrate that iQOS significantly reduces harm and the risk of tobacco-related disease. Moreover, Philip Morris was required to promptly disclose (but did not) that some of the studies it conducted showed that iQOS contained compounds of toxicological concern in higher quantities than in conventional cigarettes.

242. On October 26, 2017, the Company filed a Form 10-Q for the quarter ended September 30, 2017 (the "3Q 2017 10-Q") with the SEC, which contained signed certifications pursuant to SOX by Defendants Calantzopoulos and Olczak, attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

243. The 3Q 2017 10-Q stated the following regarding iQOS:

> ***We conduct rigorous scientific assessments of our RRP platforms*** to substantiate that they reduce exposure to HPHCs and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking. ***We draw upon a team of expert scientists*** . . . from a broad spectrum of scientific disciplines and our extensive learnings of adult consumer preferences to develop and assess our RRPs.

244. The statements referenced above in ¶243 were materially false and misleading when made for the reasons set forth in ¶158 above.

245. The 3Q 2017 10-Q incorporated the risk factor disclosures identified in Philip Morris's 2016 Form 10-K, which were materially false and misleading for the reasons discussed in ¶203.

246. In October 2017, Philip Morris published Issue 3 of its Scientific Update for Smoke-Free Products ("Scientific Update Issue 3"). In the introductory section, Defendant Peitsch highlighted that the Company's "mission requires a solid scientific foundation to demonstrate that less harmful products can exist. This requires that we conduct excellent science while adhering to the highest quality standards and that we transparently share our study results." The Company represented the following with respect to its assessment progress: "***Our studies on EHTP, which include a large number of nonclinical and clinical studies, are very advanced and point in the direction of risk reduction and the potential to improve public health***."

247. The statements referenced in ¶246 above that the Company's non-clinical and clinical studies of electronically heated cigarettes, *i.e.*, iQOS, which are "very advanced," "point in the direction of risk reduction" were materially false and misleading when made because:

(a) the scientific evidence did not support Philip Morris's claim of risk reduction;

(b) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators;

(c) the clinical studies suffered from other deficiencies such as the duration of the studies were insufficient to provide meaningful data; and

(d) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

248. The Scientific Update Issue 3 represented that "PMI measured 54 harmful or potentially harmful compounds (HPHCs) in the EHTP [Electronically Heated Tobacco System]

aerosol compared to a standard reference cigarette (3R4F). The HPHCs flagged by the FDA and the International Agency for Research on Cancer (IARC) were reduced on average by 90%-95%."

249. In Scientific Update Issue 3, the Company also reported the following results of its clinical trials on iQOS:

> ***The clinical trials are conducted following Good Clinical Practices*** . . . The eight completed studies demonstrated that EHTP . . .
>
> > 2. ***significantly reduces exposure to 15 harmful toxicants in adult smokers who switched to EHTP to a degree approaching that of cessation over the study period*** (see Figure 5); and
> >
> > 3. ***led to favorable changes in clinically relevant risk markers linked to smoking-related diseases*** and known to reverse upon cessation over the study period.

250. The statements referenced in ¶¶248-49 above that in iQOS, certain HPHCs were reduced by 90-95%, that the clinical studies showed significantly reduced exposure to 15 harmful toxicants to levels approaching cessation and favorable changes in clinically relevant risk markers of diseases, and that its iQOS clinical trials complied with GCP were materially false and misleading when made because they failed to disclose that:

(a) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced;

(b) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

251. The Company's Scientific Update Issue 3 concluded:

> PMI developed an assessment program in line with the stepwise approach also espoused by the FDA. Applying this program to its EHTP, PMI has seen that the significant reductions in the harmful or potentially harmful compounds in the EHTP aerosol compared with cigarette smoke are reflected in significant reductions in each progressive step of the program . . . . These results gave us confidence to apply for EHTP through the MRTP pathway.

252. The statements referenced in ¶251 above that Philip Morris's assessment program was in line with FDA requirements and showed significant reductions in HPHCs in the aerosol of EHTPs (*i.e.*, iQOS) compared to cigarette smoke, giving the company "confidence" to apply for an MRTP designation were materially false and misleading when made because they failed to disclose that:

(a) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced; and

(b) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

253. On December 12, 2017, Philip Morris issued a press release announcing its "latest scientific update for smoke-free products on clinical program" and included a link to that report. In the report, entitled Scientific Update for Smoke-Free Products Issue 4, the Company represented that its "studies on EHTP, which include a large number of non-clinical and clinical

studies, are very advanced and point in the direction of risk reduction and potential to improve public health."

254. The statements referenced in ¶253 above that Philip Morris's studies were "very advanced" and "point in the direction of risk reduction" were materially false and misleading when made because the evidence did not in fact support a claim for risk reduction, as evidenced by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced.

255. The Scientific Update Issue 4 contained an interview with Defendant Picavet, discussing how Philip Morris supposedly applies best practices in its clinical research of iQOS. This interview occurred as *Reuters* was on the cusp of publishing irregularities in Philip Morris's clinical trials, including the existence of tainted urine samples and the use of unqualified investigators. Picavet's interview was likely orchestrated to spin the truth and portray Philip Morris as transparent (which it was not):

> Q: What guidelines does PMI hold itself to in its clinical research program?
>
> A: ***Guidelines for Good Clinical Practices (GCP)*** as issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use are a set of internationally recognized principles that regulatory bodies around the world expect researchers to follow when conducting clinical studies . . . Like other organizations, ***PMI abides by these principles for our clinical research, as well as following the recommendations in the FDA's 2012 Draft Guidance on Modified Risk Tobacco Products.***

256. The statements referenced in ¶255 above that Philip Morris abides by GCP and the FDA's Draft Guidance for MRTPs were materially false and misleading when made because the clinical studies did not comply with GCP or with the FDA's guidance. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies, the durations of the studies were insufficient to provide meaningful data, and contaminated urine

samples were used in some of the studies, invalidating their results. Philip Morris failed to provide robust scientific evidence to demonstrate that iQOS significantly reduces harm and the risk of tobacco-related disease. Moreover, Philip Morris was required to promptly disclose (but did not) that some of the studies it conducted showed that iQOS contained compounds of toxicological concern in higher quantities than in conventional cigarettes.

257. In the staged interview meant to portray Philip Morris as transparent and compliant with industry standards, and to preempt the stunning irregularities that would soon be exposed by *Reuters*, Picavet discussed a 2013 clinical study that involved "a few participants [that] produced an excessive quantity of urine in a 24-hour period, which is quite uncommon." Picavet said that "[t]he subjects confirmed drinking increased amounts of water during each of the study days, all medical tests came back normal and the study subjects did not show any signs of medical concern." An audit was performed and "concluded that the study site had correctly followed all processes as required by the study protocol and GCP . . . "

258. The statements referenced in ¶257 that a 2013 clinical trial involved "a few participants [that] produced an excessive quantity of urine in a 24-hour period, which is quite uncommon" but that all subjects "confirmed drinking increased amounts of water," that the "medical tests came back normal" with no "signs of medical concern," and that the Company followed study protocol and GCP were materially false and misleading when made because they failed to disclose that the individuals produced urine samples of 12-18 liters, an impossible amount of urine a human being can produce, as normal urine samples produced by humans are between 2-4 liters. Philip Morris classified these samples as "adverse events" despite the fact that the individuals producing the huge amounts were healthy, and it used and relied on these

samples to buttress its claims that iQOS is less harmful than cigarettes. These samples should not have been marked as "adverse events" but instead should have been excluded from the study.

259. Picavet also affirmed that Philip Morris "***ha[s] multiple proactive controls in place to ensure study integrity and adherence to GCP . . . these controls are also designed to detect non-adherence to GCP and trigger appropriate remediation actions where issues are found***."

260. Picavet further underscored Philip Morris's adherence to GCP:

> . . . ***PMI is committed to strictly following these [GCP] standards***. The guidelines are not only integral to maintaining the validity of the data, but also to its transparency, participant safety and overall ethical conduct. Our hope is that our adherence to these principles will allow others to see our research for what we believe it is: a significant contribution to evolving today's scientific knowledge on better alternatives to cigarettes for the millions who smoke around the world.

261. The statements referred to in ¶¶259-60 above that Philip Morris has "multiple proactive controls in place to ensure study integrity and adherence to GCP . . . these controls are also designed to detect non-adherence to GCP and trigger appropriate remediation" and that Philip Morris is following GCP standards were materially false and misleading when made because the Company's scientific studies did not comply with GCP. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies, and contaminated urine samples were used in some of the studies, invalidating their results.

262. The Scientific Update Issue 4 represented that "***[o]ur [clinical] research meets rigorous standards***" and "***[o]ur studies meet a wide range of internationally accepted research . . . standards***."

263. The statements referred to in ¶262 above that Philip Morris clinical studies meet "rigorous standards" and a "wide range of internationally accepted research standards" were materially false and misleading when made because the Company's scientific studies did not

comply with GCP. For example, the clinical trial investigators were unqualified and lacked adequate resources to conduct the studies, the durations of the studies were insufficient to provide meaningful data, and contaminated urine samples were used in some of the studies, invalidating their results.

264. Additionally, the Company made the following disclosures in Scientific Update Issue 4 about its research results on iQOS:

> On average, a reduction of about 90% of harmful and potentially harmful constituents (HPHCs) was measured in the aerosol of EHTP compared against the levels of HPHCs in smoke of commercially available cigarettes.

265. The statements referred to in ¶264 above that Philip Morris's research results show a 90% reduction in HPHC were materially false and misleading when made because:

(a) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced; and

(b) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

266. On December 2017, Philip Morris submitted its Briefing Document to the Tobacco Products Scientific Advisory Committee of the FDA, which was also released publicly. There, Philip Morris represented that "iQOS significantly reduces harm and the risk of tobacco-related disease to individual tobacco users." The Company also stated that the results of all its nonclinical studies "confirm[ed] that iQOS aerosol does not introduce any new or increased risks compared with tobacco smoke." Philip Morris further represented that its research results "consistently showed that the biological impact of switching to iQOS was directionally aligned with, and of similar magnitude to, smoking cessation."

267. The statements referred to in ¶266 above that "iQOS significantly reduces harm and the risk of tobacco-related disease to individual tobacco user," that "iQOS aerosol does not introduce any new or increased risks compared with tobacco smoke," and that switching iQOS is akin to smoke cessation were materially false and misleading when made because:

(a) the evidence did not in fact support a claim for risk reduction, as demonstrated by the fact that, for example, the studies were of short duration and less exposure in biomarkers did not mean the risks of harm or disease were reduced;

(b) some of the clinical study results were invalid because Philip Morris failed to comply with GCP by including, for example, tainted urine samples and by using unqualified investigators; and

(c) other scientific studies conducted by Philip Morris showed that iQOS actually contained certain compounds of toxicological concern in higher quantities than in conventional cigarettes.

3. The 2018 Statements

268. In January 2018, Philip Morris posted on its official website the following statements made by Defendant Calantzopoulos: "Scientific substantiation is fundamental. I think we are producing the best science you can produce in the field today." These statements were also posted by Philip Morris on its official website in February, March, and April 2018.

269. The statements referenced above in ¶268 were materially false and misleading when made for the reasons set forth in ¶166 above.

270. On February 13, 2018, the Company filed a Form 10-K for the fiscal year ended December 31, 2017 (the "2017 10-K") with the SEC, which contained SOX signed certifications by Defendant Calantzopoulos, attesting to the accuracy of financial reporting, the disclosure of

any material changes to the Company's internal controls over financial reporting, and the disclosure of all fraud.

271. The 2017 10-K stated the following regarding IQOS:

> Reduced-Risk Products . . . ***We conduct rigorous scientific assessments of our RRP platforms*** to substantiate that they reduce exposure to HPHCs and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking. ***We draw upon a team of expert scientists*** . . . from a broad spectrum of scientific disciplines and our extensive learnings of adult consumer preferences to develop and assess our RRPs.

272. The statements referenced above in ¶271 were materially false and misleading when made for the reasons set forth in ¶158 above.

273. In addition, the 2017 10-K contained the following risk disclosure:

> ***We may be unsuccessful in our attempts to introduce reduced-risk products, and regulators may not permit the commercialization of these products or the communication of scientifically substantiated risk-reduction claims.***
>
> Our key strategic priorities are: to develop and commercialize products that present less risk of harm to adult smokers who switch to those products versus continued smoking; and to convince current adult smokers who would otherwise continue to smoke to switch to those RRPs. For our efforts to be successful, we must: develop RRPs that such adult smokers find acceptable alternatives to smoking; conduct rigorous scientific studies to substantiate that they reduce exposure to harmful and potentially harmful constituents in smoke and, ultimately, that these products present, are likely to present, or have the potential to present less risk of harm to adult smokers who switch to them versus continued smoking; and effectively advocate for the development of science-based regulatory frameworks for the development and commercialization of RRPs, including communication of scientifically substantiated information to enable adult smokers to make better consumer choices. We might not succeed in our efforts. If we do not succeed, but others do, we may be at a competitive disadvantage. Furthermore, we cannot predict whether regulators will permit the sale and/or marketing of RRPs with scientifically substantiated risk-reduction claims. Such restrictions could limit the success of our RRPs.

274. The risk factor referenced in ¶273 above was materially false and misleading when made, because it failed to disclose: (1) that the risk that Philip Morris would not obtain approval from the FDA to sell iQOS in the United States as a modified risk tobacco product was

undermined by the fact that: (i) some of the iQOS clinical study results were invalid, as Philip Morris failed to comply with GCP and other generally accepted clinical study practices; and (ii) other scientific studies conducted by Philip Morris showed that iQOS contained compounds of toxicological concern in higher quantities than in conventional cigarettes, all of which were known to Defendants; and (2) the risk that the market for early adopters and innovators in Japan might have reached saturation such that growth of iQOS and HeatStick sales would slow in the first quarter of 2018.

B. Materially False and Misleading Statements Concerning Sales Growth in Japan

275. On February 8, 2018, Philip Morris issued a press release announcing its results for the quarter and year ended December 31, 2017, which it filed with the SEC on Form 8-K (the "2/8/18 Press Release"). The 2/8/18 Press Release stated that the Company's net revenues, excluding excise taxes, had increased 7.7% for the year to $28.7 billion, up 9.4% year-over-year excluding unfavorable currency impacts. For the quarter, the Company reported that its cigarette and heated tobacco unit shipment volumes had increased by 3.8% to 212.1 billion and its net revenues, excluding excise taxes, had increased by 19% to $8.3 billion. The 2/8/18 Press Release also provided a 2018 full-year forecast that projected "[n]et revenue growth, excluding excise taxes, of ***over*** 8.0%, excluding currency."

276. Defendant Calantzopoulos was quoted in the 2/8/18 Press Release, stating that the Company's strong momentum from its fourth quarter results would continue in the new year. The 2/8/18 Press Release stated as follows:

> A strong fourth-quarter performance helped drive robust full-year results, exemplified by currency-neutral, double-digit adjusted earnings per share growth, despite previously disclosed challenges in Russia and Saudi Arabia . . . .
>
> The excellent performance of our flagship smoke-free product IQOS – not only in Asia, but also in the vast majority of our launch geographies – underscored its

> great promise and the commitment of our employees to lead the transformation of our industry towards a smoke-free future. ***Continued investment behind IQOS in 2018 is expected to further drive its positive momentum***.

277. The statement referenced above in ¶276 that "momentum" for iQOS in 2018 was "positive" was materially false and misleading when made, because it failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statement was made:

(a) that favorable sales trends Philip Morris experienced in the fourth quarter of 2017 had not continued through the first quarter of 2018;

(b) that shipments of the Company's heated tobacco units were on track to decline 39% sequentially in the first quarter of 2018;

(c) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling, and Defendants were already experiencing plateauing market share growth in Japan, the Company's primary market for iQOS;

(d) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(e) as a result of the foregoing, "momentum" for iQOS was, in fact, not "positive."

278. Following the issuance of the 2/8/18 Press Release, Philip Morris held a conference call with analysts and investors to discuss its financial results and operations. Defendants Calantzopoulos and King participated on the call and reiterated the Company's financial results as set forth in the 2/8/18 Press Release. During the call, Defendant Calantzopoulos discussed the performance of both iQOS devices and HeatSticks in Japan in 2017 and Defendants' expectations for the first quarter of 2018, stating as follows:

> In Japan, the spectacular performance of iQOS drove our results in 2017. Total shipment volume increased by nearly 30%, driven by the strong growth in HeatSticks demand and the increase in HeatSticks inventory level. Excluding estimated inventory movements, total shipment volume increased by 13.1%.
>
> The favorable inventory movements primarily reflected an ***increasing demand for HeatSticks, which we expect to grow further in the first quarter following a planned lifting of the restriction on iQOS device sales; the establishment of appropriate distributor inventory levels of heated tobacco units, given the current high dependence on a single manufacturing center; and the transition from air to sea freight of heated tobacco unit shipments, largely completed in the fourth quarter of 2017.***

279. The statement referenced above in ¶278 that in Japan there was "increasing demand for HeatSticks, which we expect to grow further in the first quarter" was materially false and misleading when made, because it failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statement was made:

(a) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(b) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

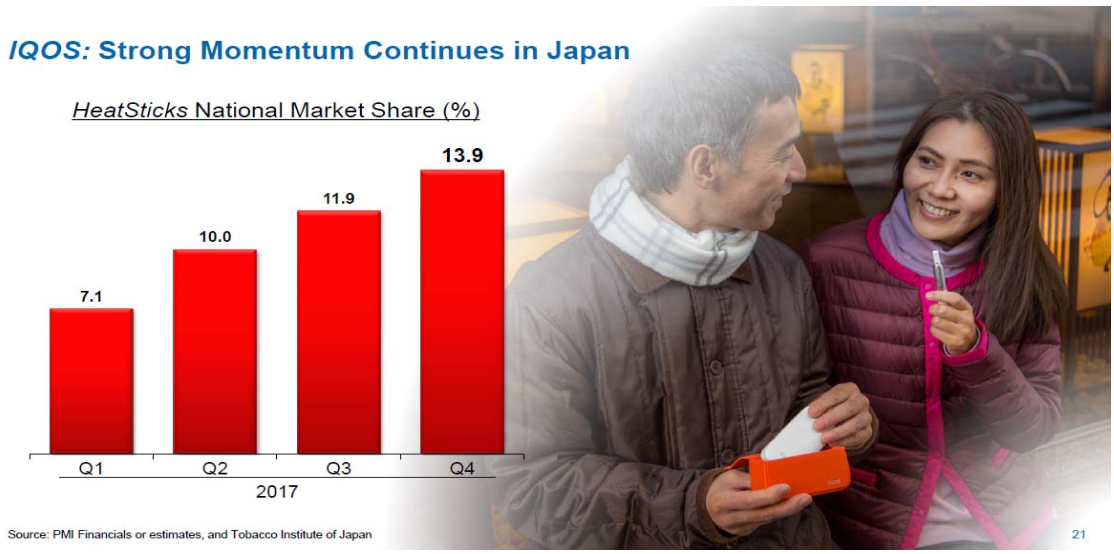
(c) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(d) as a result of the foregoing, demand for HeatSticks in Japan was not "increasing" and was not set to "grow further" in the first quarter of 2018.

280. Defendant Calantzopoulos also underscored various factors that set Philip Morris up for a favorable 2018 in connection with iQOS. While showing the below slide, he stated, in pertinent part, as follows:

To close on 2017, I will cover in more detail the strong momentum of IQOS across geographies, beginning with Japan. As seen on this slide, HeatSticks recorded strong sequential quarterly share growth throughout the year, despite capacity limitations, first related to HeatSticks, and then on IQOS devices, as well as the increased availability of competitors' heated tobacco products.

We thus begin 2018 in excellent shape, with the supply of HeatSticks no longer an issue. The shipments of HeatSticks now shifted from air to lower-cost sea freight, and the capacity limits on IQOS device is behind us as of this month.



281. The statements referenced above in ¶280 that Philip Morris was "begin[ning] 2018 in excellent shape" in Japan and that, for iQOS, "Strong Momentum Continues in Japan" were materially false and misleading when made, because they failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statements were made:

(a) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(b) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

(c) that Philip Morris was experiencing plateauing market share growth in Japan;

(d) that shipments of HeatSticks to Japan were on track to decline by almost seven billion units quarter-on-quarter in the first quarter of 2018;

(e) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(f) as a result of the foregoing, the Company was neither in "excellent shape" in Japan nor was its iQOS momentum in Japan "strong" or set to "continue[]."

282. Moreover, Defendant Calantzopoulos' statement that the "supply of HeatSticks [is] no longer an issue" created a duty to disclose that demand for HeatSticks had materially declined.

283. Defendant Calantzopoulos was also asked by an analyst from Goldman Sachs about the Company's outlook for combustible cigarette and HeatStick volume in Japan in 2018. His exchange with the analyst was, in pertinent part, as follows:

> **Eunjoo Hong - Goldman Sachs Group Inc., Research Division - MD, Co-Head of the GIR Asian Professionals Network, and Senior Analyst**
>
> All right. I think I get that. Separately in -- so Japan. So first on iQOS, it sounds like if you kind of look at the retail market share performance and your shipment figures, you're sort of a $12 billion or so in terms of additional shipments in 2017 related to favorable inventory movement. And I think the way we should model this is the space in the base and so we're not going to see an adverse impact in 2018. So I just wanted to clarify that, number one. And number two, JT's view of the total market decline in 2018 seems pretty sizable. So I'm just wondering what you're thinking in terms of the combustible plus the HeatStick volume outlook for Japan, if there is anything changing from a secular perspective that you see?
>
> **André Calantzopoulos - Philip Morris International Inc. - CEO & Director**
>
> Yes. Look, we had to build these inventories for the reasons I explained, so I don't see this decreasing. If I see anything as the volume goes up, it has to be adjusted, obviously, upwards over time. I'm talking our HeatSticks inventory. Obviously, we have reduced the combustible inventory to reflect the volumes of combustibles going down, and we'll continue adjusting this during the year as it unfolds. So that's to answer your first question. The second one is, ***look, we have***

> ***our own projection for total market in Japan, including obviously HeatSticks. And there's nothing in the horizon that would affect -- that would cause any change in what happened in the previous years. . . .***

284. The statement referenced above in ¶283 that "there's nothing in the horizon that would affect – that would cause any change in what happened in the previous years" in Japan was materially false and misleading when made, because it failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statements were made:

(a) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(b) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

(c) that Philip Morris was experiencing plateauing market share growth in Japan;

(d) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(e) as a result of the foregoing, the shipment volume of HeatSticks to Japan was on track to decline by almost seven billion units quarter-on-quarter in the first quarter of 2018.

285. On February 13, 2018, Philip Morris filed the 2017 10-K, which was signed by, *inter alia*, Defendants Calantzopoulos and King. The 2017 10-K repeated and restated the annual and quarterly financial results and 2018 outlook of "***over*** 8.0%" net revenue growth provided in the 2/8/18 Press Release. In addition, the 2017 10-K stated that the favorable

sequential sales trends experienced by Philip Morris in Japan in the fourth quarter of 2017 were set to continue in the first quarter of 2018. For example, the 2017 10-K stated as follows:

> Excluding the favorable net impact of estimated cigarette and heated tobacco unit inventory movements of approximately 3.3 billion units, our total shipment volume decreased by 3.1%. ***The favorable inventory movements were driven primarily by approximately 8.5 billion units net in Japan reflecting: the increasing demand for HeatSticks, anticipated to further increase in the first quarter of 2018 following a planned lifting of the restriction on IQOS device sales; the establishment of appropriate distributor inventory levels of heated tobacco units, given the current high dependence on a single manufacturing center; and the transition from air freight to sea freight of heated tobacco units, largely completed in the fourth quarter of 2017***.

286. The statement referenced above in ¶285 that demand for HeatSticks in Japan was "anticipated to further increase in the first quarter of 2018" was materially false and misleading when made, because it failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statements were made:

(a) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(b) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

(c) that demand for iQOS in Japan was slowing as a consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(d) as a result of the foregoing, the demand for HeatSticks in Japan in the first quarter of 2018 was not "anticipated to further increase."

287. On February 21, 2018, Defendants Calantzopoulos, King and Olczak each presented on behalf of Philip Morris at the CAGNY conference. In his prepared remarks, Defendant Calantzopoulos stated that Philip Morris should be considered a "***growth stock***,"

because "***8%-plus currency-neutral net revenue growth is not just a 2017 or 2018 phenomenon***" for the Company, but would likely continue into the future based on existing trends and initiatives in the business.

288. The statements referenced above in ¶287 that Philip Morris was a "growth stock" and that "8%-plus currency-neutral net revenue growth is not just a 2017 or 2018 phenomenon" were materially false and misleading when made, because they failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statements were made:

(a) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(b) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

(c) that Philip Morris was experiencing plateauing market share growth in Japan;

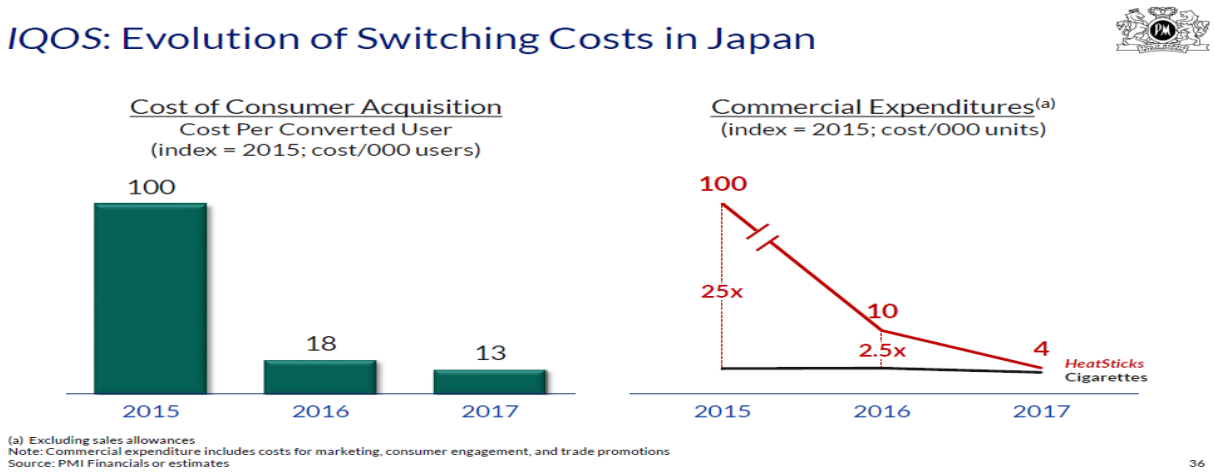
(d) that shipments of HeatSticks to Japan were on track to decline by almost seven billion units quarter-on-quarter in the first quarter of 2018;

(e) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(f) as a result of the foregoing, Defendants were poised to lower their 2018 guidance of 8% plus currency-neutral net revenue growth.

289. During his portion of the CAGNY presentation, while showing the below slide, Defendant Olczak highlighted the Company's purported success in converting Japan's existing adult population to heated tobacco products, stating as follows:

> ***As the understanding of the category and its benefits are established in adult smoker communities, IQOS starts enjoying word of mouth, as adult smokers share experiences with friends and peers.*** Although this varies according to countries and cultures, it is universally true.



290. The statement referenced above in ¶289 regarding "word of mouth" amongst adult smokers in Japan and the impact it was having on getting this demographic of smokers to switch to iQOS was materially false and misleading when made, because it failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statements was made:

(a) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(b) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

(c) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(d) as a result of the foregoing, adult smokers in Japan were in fact switching to iQOS at a lower rate than the Company had previously experienced.

291. Defendant Olczak also announced the Company's plans to further penetrate into existing iQOS markets in 2018, stating as follows:

> For 2018, our priority is to go ***deeper with IQOS into our existing launch markets***. We feel comfortable with the number of markets where we are present, and plan to further deploy our many learnings across these markets to accelerate growth.

292. The statement referenced above in ¶291 that Defendants planned to "go deeper with iQOS into our existing launch markets" was materially false and misleading when made, because it failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statement was made:

(a) that Defendants were already experiencing plateauing market share growth in Japan, the Company's primary market for iQOS;

(b) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(c) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

(d) that shipments of HeatSticks to Japan were on track to decline by almost seven billion units quarter-on-quarter in the first quarter of 2018;

(e) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(f) as a result of the foregoing, the Company already faced significant obstacles preventing it from further penetrating into its most important existing market for iQOS.

293. Defendant Olczak further represented that accelerating iQOS growth trends experienced at the end of 2017 were continuing into the first quarter of 2018, including in Japan. While showing the below slide as part of his presentation, he stated as follows:

> [W]e recorded sequential growth in our heated tobacco unit national market shares in 2017. ***This growth trend continued in January of 2018***, with standout performances in Korea, Portugal and Romania.

294. The statement referenced above in ¶293 that the "growth trend" in iQOS' Japanese national market share "continued in January 2018" was materially false and misleading when made, because it failed to disclose and/or misrepresented the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statement was made:

(a) that there was a risk that the January market share numbers for Japan that Defendants were reporting were inflated because of the timing of competitor shipments;

(b) that Philip Morris was experiencing plateauing market share growth in Japan;

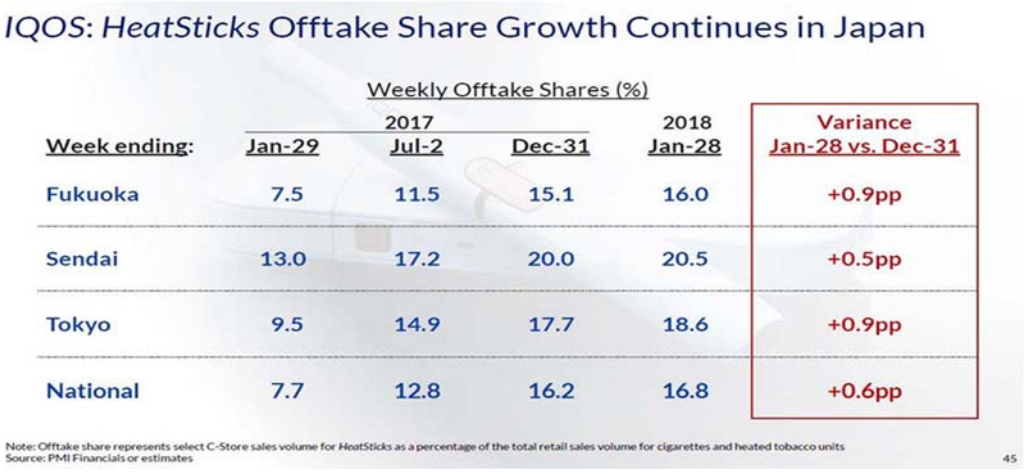
(c) that shipments of HeatSticks to Japan were on track to decline by almost seven billion units quarter-on-quarter in the first quarter of 2018;

(d) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim; and

(e) as a result of the foregoing, sequential growth in the Company's HeatStick national market share in Japan was lower than the rate that Defendants were reporting and was not continuing in the first quarter of 2018.

295. In addition, Defendant Olczak reported on the growth of the Company's weekly offtake shares—an indicator of in-market sales—for HeatSticks in January in Japan. Olczak showed the following slides and stated as follows:

> ***Our weekly offtake shares in Japan continued to grow in January, both nationally and in the prefectures where the heated tobacco category is the most mature from a competitive standpoint***: Fukuoka, Sendai and Tokyo.



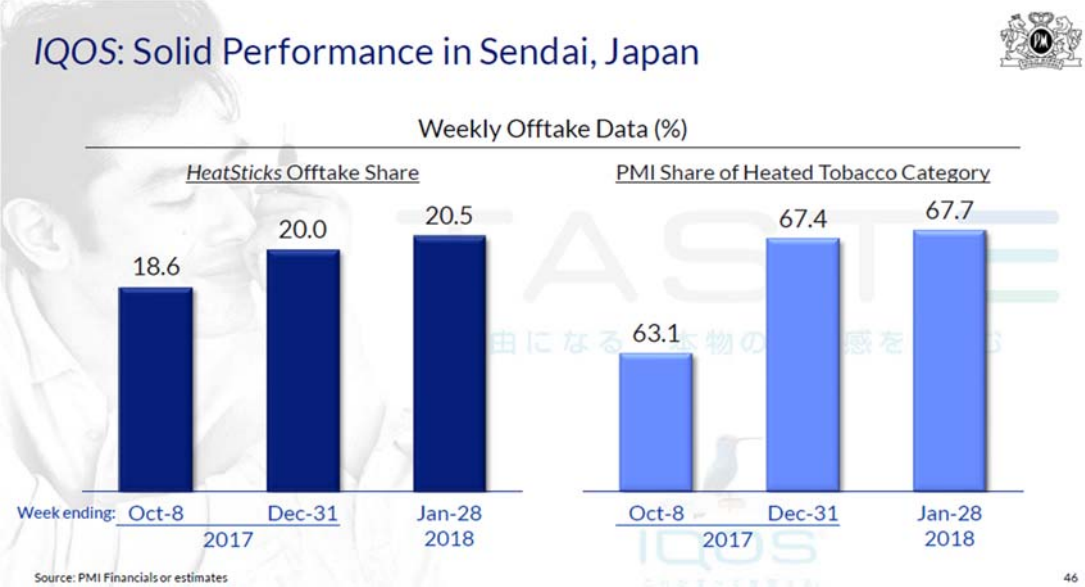
IQOS: HeatSticks Offtake Share Growth Continues in Japan

	Weekly Offtake Shares (%)				
	2017			2018	Variance
Week ending:	Jan-29	Jul-2	Dec-31	Jan-28	Jan-28 vs. Dec-31
Fukuoka	7.5	11.5	15.1	16.0	+0.9pp
Sendai	13.0	17.2	20.0	20.5	+0.5pp
Tokyo	9.5	14.9	17.7	18.6	+0.9pp
National	7.7	12.8	16.2	16.8	+0.6pp

Note: Offtake share represents select C-Store sales volume for *HeatSticks* as a percentage of the total retail sales volume for cigarettes and heated tobacco units
Source: PMI Financials or estimates

45

> In Sendai specifically, our weekly offtake ***share growth in January drove further growth in our heated tobacco category shar***e. In fact, the category's growth was ***driven primarily by IQOS***.

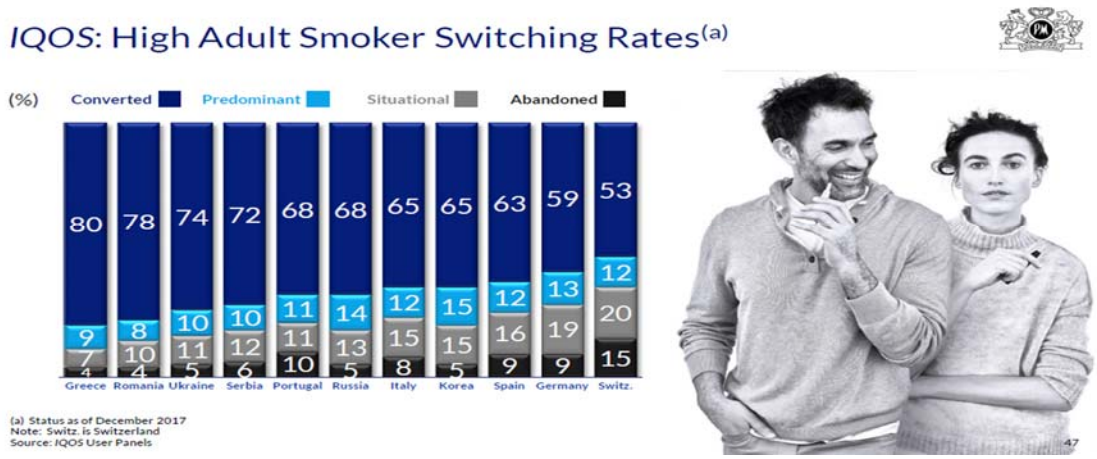


296. The statements referenced above in ¶295 touting the weekly offtake shares for HeatSticks in Japan during January 2018 were materially false and misleading when made, because by speaking about continued growth of HeatSticks in Japan, it created a duty to disclose that Philip Morris was currently experiencing plateauing market share growth in Japan as a result of saturating the younger, easier-to-convert iQOS user base, that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim, and that shipments of HeatSticks to Japan were on track to decline by almost seven billion units quarter-on-quarter, which Defendants knew, or recklessly disregarded.

297. In addition, Defendant Olczak touted the high switching rates from cigarettes to iQOS that were supposedly being achieved across various markets, especially in Japan. While showing the following slides, Olczak stated as follows:

> ***Our strong share performances for IQOS continue to be underpinned by high IQOS switching across markets, which generally reflects rates of full and predominant conversion ranging from around 70% to 90%.*** IQOS switching rates in certain markets are beginning to reflect the emerging presence of

competition in the heated tobacco category, as IQOS purchasers experiment with newly available products, even if just temporarily.



The most obvious example is Japan, where there are now several heated tobacco products. Looking at IQOS switching, an estimated 68% of IQOS purchasers have switched exclusively to the heated tobacco category.

298. The statement referenced above in ¶297 by Defendant Olczak highlighting Philip Morris's "strong share performances for IQOS," particularly in Japan, was materially false and misleading when made, because this statement created a duty to disclose the following adverse facts that Defendants knew, or recklessly disregarded, at the time the statements were made:

(a) that the Company's sales initiatives designed to convert adult smokers in Japan to iQOS were struggling;

(b) that the Company had saturated the younger, easier-to-convert, iQOS user base in Japan;

(c) that Philip Morris was experiencing plateauing market share growth in Japan; and

(d) that demand for iQOS in Japan was slowing as consumers learned of the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes and in light of other evidence rebutting that claim.

299. On April 19, 2018, Defendants stunned the market by revealing that growth in iQOS sales had slowed in Japan in the first quarter because the Company was experiencing "less-rapid-than-initially-projected growth in sales of devices to consumers in Japan in the first quarter, as we are now reaching more conservative adult smoker segments that may require, at least at first, slightly more time for adoption."

300. In addition, Philip Morris reported 6.2 billion HeatStick shipments to Japan in the first quarter – approximately ***7 billion*** fewer HeatSticks than the Company shipped to that market in the prior quarter – and overall first quarter HeatStick shipments of just 9.6 billion, which represented a 39% decline from the fourth quarter of 2017. As a result of these developments, Defendants lowered the Company's previously-announced net revenue growth guidance to "approximately 8.0%."

301. In response to this disappointing news, the price of Philip Morris common stock plummeted, falling from $101.44 per share on April 18, 2018 to close at $85.64 per share on April 19, 2018 – a decline of $15.80 per share, or approximately 15%, on high trading volume of more than 45 million shares trading, more than 10 times greater than the average daily trading volume during the Class Period.

302. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiffs and other Class members have suffered significant losses and damages.

C. Philip Morris's Class Period SEC Filings Did Not Comply with SEC Disclosure Requirements

303. Item 7 of Form 10-K and Item 2 of Form 10-Q require SEC registrants to furnish the information called for under Item 303 of Regulation S-K [17 C.F.R. §229.303], Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A"). Among other things, Item 303 of Regulation S-K required that Philip Morris's Class Period Forms 10-K and 10-Q disclose known trends or uncertainties that had, or were reasonably likely to have, a material impact on its revenues or income from continuing operations.

304. In 1989, the SEC issued interpretative guidance associated with the requirements of Item 303 of Regulation S-K concerning the disclosure of material trends or uncertainties. In particular, the interpretative guidance states specifically that when an SEC registrant knows that a competitor has introduced to the marketplace a product similar to its own at a price less than that charged by the registrant, a known uncertainty that is reasonably likely to have a material effect on its future operating results exists, and disclosure is required. The interpretative guidance states, in pertinent part, as follows:

> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.
>
> * * *
>
> **Events that have already occurred** or are anticipated **often give rise to known uncertainties**. For example, a registrant may know that a material government contract is about to expire. The registrant may be uncertain as to whether the contract will be renewed, but nevertheless would be able to assess facts relating to

> whether it will be renewed. More particularly, **the registrant may know that a competitor has found a way to provide the same service or product at a price less than that charged by the registrant**, or may have been advised by the government that the contract may not be renewed. The registrant also would have factual information relevant to the financial impact of non-renewal upon the registrant. **In situations such as these, a registrant would have identified a known uncertainty reasonably likely to have material future effects on its financial condition or results of operations, and disclosure would be required**.

305. In 2003, the SEC issued additional interpretative guidance relating to the requirements of Item 303. Such guidance states, in pertinent part:

> ***We believe that management's most important responsibilities include communicating with investors in a clear and straightforward manner. MD&A is a critical component of that communication.*** The Commission has long sought through its rules, enforcement actions and interpretive processes to elicit MD&A that not only meets technical disclosure requirements but generally is informative and transparent.

306. Thus, the MD&A disclosures in Philip Morris's Forms 10-K and 10-Q it filed with the SEC during the Class Period were materially false and misleading because Defendants failed to disclose the known uncertainties associated with: (i) the level of saturation among the early adopters and innovators in Japan and how that would impact iQOS and HeatStick sales in 2018; (ii) consumer demand following the FDA panel's rejection of Philip Morris's claim that iQOS is safer than cigarettes based on the flawed clinical studies and other evidence rebutting that claim; and (iii) the accuracy of Philip Morris's Japanese market share number as compared to its competitors. As a result, these were events presenting known trends and uncertainties that were reasonably likely to – and, when they came to fruition during the Class Period, did – adversely affect Philip Morris's financial condition and results. The omission of this information violated the disclosure obligation imposed by Item 303.

307. In addition, Item 1A of both Form 10-K and Form 10-Q requires SEC registrants to furnish the information called for under Item 503 of Regulation S-K [17 C.F.R. §229.503],

Risk Factors. Item 503 of Regulation S-K required that Philip Morris's Class Period Forms 10-K and 10-Q disclose the most significant matters that make an investment in Philip Morris risky.

308. As detailed herein, during the Class Period, Philip Morris's Forms 10-K and 10-Q failed to disclose: (1) that the risk that Philip Morris would not obtain approval from the FDA to sell iQOS in the United States as a modified risk tobacco product was undermined by the fact that: (i) some of the iQOS clinical study results were invalid, as Philip Morris failed to comply with GCP and other generally accepted clinical study practices; and (ii) other scientific studies conducted by Philip Morris showed that iQOS contained compounds of toxicological concern in higher quantities than in conventional cigarettes, all of which were known to Defendants; and (2) the risk that the market for early adopters and innovators in Japan might have reached saturation such that growth of iQOS and HeatStick sales would slow in the first quarter of 2018.

ADDITIONAL SCIENTER ALLEGATIONS

309. As alleged herein, Defendants acted with scienter in that they knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company (or in their own name) were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. For example, Defendants knew that the studies used to support their claim that iQOS is less harmful than cigarettes were not conducted in accordance with GCP and did not support their false claims. And, in light of the fact that this news spread in the Japanese market and was an issue of significant concern, Defendants' repeated reassurances that demand for iQOS in Japan remained strong were made with knowledge of their falsity or in reckless disregard of the truth.

310. Defendants, by virtue of their receipt of information reflecting the true facts regarding Philip Morris, their control over, and/or receipt and/or modification of Philip Morris's materially false and misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.

311. Because of their positions within Philip Morris, Defendants Calantzopoulos, Olczak, King, Picavet, and Peitsch had access to non-public information about the Company's business, operations, operational trends, financial statements, markets, and present and future business prospects via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or Board of Directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, these Defendants knew, or recklessly disregarded, that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

312. The Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels and were privy to confidential proprietary information concerning the Company and its business, operations, financial statements, and financial condition, as alleged herein.

313. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent activity alleged herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the officers at the highest levels of the Company, including Defendant Calantzopoulos.

314. For example, Defendants Calantzopoulos, King, Olczak, and Picavet were all executive officers or in top management positions at Philip Morris and, at a minimum, would have been aware of key facts related to the Company's operations.

315. In addition, the fraud alleged herein relates to the core business and operations of Philip Morris so knowledge of the fraud may be imputed to Defendants. As explained herein, the entire business model of Philip Morris has been transformed to focus on replacing traditional cigarettes with "smoke free" products. iQOS is the "smoke free" product that Philip Morris is pushing to fulfill this goal.

316. Moreover, Defendants possessed substantial motives for failing to disclose that Philip Morris's clinical studies failed to comply with Good Clinical Practices and to disclose the fact that there was a significant decrease in demand for iQOS in Japan. During the Class Period, Defendant Calantzopoulos, as well as other senior Company executives, in connection with the fraudulent scheme alleged herein, sold more than $31 million worth of Philip Morris common stock, while in possession of material non-public information, as set forth below:

Filer Name	Title	Date	Shares	Price	Proceeds
Andres Calantzopoulos	Chief Executive Officer	Feb. 15, 2017 Feb. 22, 2018	35,000 49,000	$102.65 $103.66	$3,592,750 $5,079,340
			84,000		**$8,672,090**
Louis Camilleri	Chairman of the Board	Feb. 17, 2017 Oct. 24, 2017	60,000 108,979	$103.33 $108.38	$6,199,800 $11,811,144
			168,979		**$18,010,944**
Marc Firestone	General Counsel	Feb. 15, 2017 Feb. 22, 2018	17,088 13,650	$102.57 $104.63	$1,752,716 $1,428,200
			30,738		**$3,180,916**
TOTAL:			**297,717**		**$31,487,950**

317. For example, Philip Morris filed the 2016 10-K on February 14, 2017, which was signed by Defendants Calantzopoulos and Olczak. In the 2016 10-K, Defendants stated, *inter alia*, that the results from the clinical studies for iQOS conducted by the Company "are generally

consistent with the expected direction of change and indicate that switching completely to IQOS led to an overall improvement of clinical risk markers affected by smoking after only three months." The next day, Calantzopoulos sold 35,000 shares of his personally held Philip Morris shares for proceeds of nearly $3.6 million.

318. In addition, on February 22, 2018—the very day after he and Defendants King and Olczak presented at the CAGNY conference discussing the supposedly robust performance of iQOS in Japan—Calantzopoulos unloaded 49,000 shares of his personally held Philip Morris stock, for over $5 million in proceeds. This sale was the largest ever by Defendant Calantzopoulos in his position as CEO of the Company and more than 22% above his next largest sale of Philip Morris stock in at least the preceding five years.

319. This sale also occurred near peak trading prices during the Class Period and at more than $18 above the price Philip Morris shares fell to after revelations of the truth entered the market.

320. Taken collectively, Defendant Calantzopoulos' Class Period Philip Morris stock sales support an inference of scienter because these sales were timed to capitalize on Philip Morris's inflated stock price before the news was revealed to the market that, despite Defendants' positive statements about iQOS growth, iQOS market share growth in Japan was actually plateauing in the first quarter of 2018.

321. The allegations above also establish a strong inference that Philip Morris as an entity acted with corporate scienter throughout the Class Period, as its officers, management, and agents, including, but not limited to, the Individual Defendants, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to

disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing Philip Morris's true operating condition and present and expected financial performance from the investing public. By concealing these material facts from investors, Philip Morris maintained and/or increased the prices of its artificially inflated securities throughout the Class Period.

LOSS CAUSATION/ECONOMIC LOSS

322. During the Class Period, as detailed above, Philip Morris and the Individual Defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the prices of Philip Morris's securities, and operated as a fraud or deceit on Class Period purchasers of Philip Morris securities by misrepresenting the Company's business and prospects. Later, when Defendants' prior misrepresentations and fraudulent conduct became known to the market, the price of Philip Morris's securities declined as the prior artificial inflation came out of the price over time. As a result of their purchases of Philip Morris securities during the Class Period, Plaintiffs and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

323. On December 20, 2017, *Reuters* released a comprehensive investigative report detailing irregularities in the clinical trials underpinning the Company's FDA application for iQOS in the United States. *Reuters* highlighted significant deficiencies within the clinical trials, such as tainted urine samples and shortcomings in the training and professionalism of the lead investigators, *i.e.*, lack of English skills from researchers, failure to follow basic procedure to obtain informed consent, and uninformed and unsophisticated investigators, among other concerns.

324. On this news, the Company's stock price fell $3.75 per share or approximately 3.5%, to close at $104.37 per share on December 20, 2017, damaging investors.

325. Then, on January 25, 2018, *The New York Times* published an article entitled "F.D.A. Panel Rejects Philip Morris's Claim That Tobacco Stick Is Safer Than Cigarettes," reporting the FDA's Tobacco Products Scientific Advisory Committee had recommended for the rejection of Philip Morris's bid to market iQOS as safer than traditional cigarettes in the United States. According to the article, among other things, the Committee questioned the quality of the science behind the company's safety claims, and in an eight-to-one vote, the "panel rejected the company's contention that 'scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.'"

326. On this news, the Company's stock price fell $3.11 per share or 2.81%, to close at $107.49 on January 25, 2018.

327. On April 19, 2018, Philip Morris reported its financial results for the quarter ended March 31, 2018. The Company revealed that it had only achieved cigarette and heated tobacco unit shipment volumes of 173.8 billion units, a decline of 2.3%. This result was significantly worse than consensus estimates of a total volume decline of only 0.6%. Similarly, the Company's cigarette volumes declined 5.3%, despite being compared against an 11.5% decline from the prior-year quarter. The Company's heated tobacco unit sales fared particularly poorly, with quarterly sales of only 9.6 billion units compared to consensus estimates of 13.2 billion units, which represented a sequential ***decline*** of nearly 39%.

328. Defendants further revealed that growth had slowed in the same key Japan markets that had been highlighted by Defendants. In addition, the release revealed that the Company was no longer positioned to achieve net revenue growth greater than 8%,

notwithstanding Defendant Calantzopoulos' statement made more than halfway through the disappointing quarter, *i.e.,* suggesting that this growth rate would be maintained for the foreseeable future. Later, in connection with its second quarter 2018 results, Philip Morris revealed that it was only on track to achieve 3% to 4% projected currency neutral net revenue growth for 2018.

329. While the Defendants disclosed that the Company's sales initiatives were having limited success in converting "more conservative adult smoker segments," they further revealed the troubling extent of the problem on an earnings call held that same day. On the call, Defendant King disclosed that the Company's sale of heated tobacco units in Japan had hit a "plateau." Rather than being needed to meet growing demand as was represented to investors, Defendant King claimed that Philip Morris's increased shipments to Japan at the end of 2017 had come "close to saturating the early adopters and innovators," as sales initiatives had stalled throughout the quarter. Defendant King also revealed that the Company had achieved Japan market share for March of 15.6%, which implied that February—the same month during which Defendants had touted a "growing" Japan market share of "16.3%"—had been the ***worst month*** of the quarter.

330. On this news, the Company's stock price fell $15.80 per share, or more than 15%, to close at $85.64 per share on April 19, 2018. This represented the worst daily decline for the Company's stock in nearly a decade.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

331. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's stock traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

(e) Plaintiffs and other members of the Class purchased Philip Morris common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

332. At all relevant times, the markets for Philip Morris securities were efficient for the following reasons, among others:

(a) as a regulated issuer, Philip Morris filed periodic public reports with the SEC;

(b) Philip Morris regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services;

(c) Philip Morris was followed by several securities analysts employed by major brokerage firm(s) who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firm(s) and that were publicly available and entered the public marketplace; and

(d) Philip Morris's common stock was actively traded in an efficient market, namely the NYSE, under the ticker symbol "PM."

333. As a result of the foregoing, the market for Philip Morris securities promptly digested current information regarding Philip Morris from publicly available sources and reflected such information in the prices of Philip Morris's securities. Under these circumstances, all purchasers of Philip Morris securities during the Class Period suffered similar injury through their purchase of Philip Morris securities at artificially inflated prices and the presumption of reliance applies.

334. Further, to the extent that the Defendants concealed or improperly failed to disclose material facts with regard to the Company, Plaintiffs are entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

NO SAFE HARBOR

335. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or

misleading, and/or the forward-looking statement was authorized or approved by an executive officer or top management of Philip Morris who knew that the statement was false when made.

336. In connection with the CAGNY conference presentation, Defendants included a slide of "Forward-Looking and Cautionary Statements." These purported cautionary statements were not meaningful, because they failed to disclose, *inter alia*, the risk that the Company had already saturated the younger, easier-to-convert, iQOS user base in Japan, which Defendants would later admit they were aware of, by telling investors on April 19, 2018 that "we knew the consumer dynamic that we had – close to saturating the early adopters and innovators."

337. In addition, the "Forward-Looking and Cautionary Statements" that Defendants provided at the CAGNY conference failed to disclose the risk that the Japanese market share number they were presenting for January 2018 was inflated due to competitor shipment timings, which Defendants acknowledged they were aware of and analysts complained should have been disclosed.

CLASS ACTION ALLEGATIONS

338. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons or entities who purchased or otherwise acquired Philip Morris securities between July 26, 2016 and April 18, 2018, inclusive (the "Class"). Excluded from the Class are Defendants, members of the immediate family of each of the Individual Defendants, any subsidiary or affiliate of Philip Morris, and the directors and officers of Philip Morris and their families and affiliates at all relevant times.

339. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of July 23, 2018, there were 1,554,506,845 shares outstanding of Philip Morris's common stock.

340. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions which may affect individual Class members include:

(a) Whether the Exchange Act was violated by Defendants;

(b) Whether Defendants omitted and/or misrepresented material facts;

(c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the prices of Philip Morris securities were artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

341. Plaintiffs' claims are typical of those of the Class because Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.

342. Plaintiffs will adequately protect the interests of the Class and have retained counsel experienced in securities class action litigation. Plaintiffs have no interests that conflict with those of the Class.

343. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CLAIMS FOR RELIEF

COUNT I

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

344. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

345. During the Class Period, Defendants disseminated or approved the false statements above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations or omissions and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

346. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Philip Morris securities during the Class Period.

347. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Philip Morris securities. Plaintiffs and the Class would not have purchased Philip Morris securities at the prices they paid, or at all, if they

had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

348. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Philip Morris securities during the Class Period.

COUNT II

For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

349. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

350. The Individual Defendants acted as controlling persons of Philip Morris within the meaning of Section 20(a) of the Exchange Act. By virtue of their positions and their power to control public statements about Philip Morris, the Individual Defendants had the power and ability to control the actions of Philip Morris and its employees. By reason of such conduct, Defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Federal Rule of Civil Procedure 23;

B. Awarding Plaintiffs and the members of the Class damages and interest;

C. Awarding Plaintiffs' reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive relief or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

Dated: May 10, 2019

Respectfully submitted,

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CERTIFICATION PURSUANT TO FEDERAL SECURITIES LAWS

TEAMSTERS LOCAL 710 PENSION FUND ("Plaintiff") declares:

1. Plaintiff has reviewed a complaint and authorized its filing. Plaintiff has authorized the filing of a motion for appointment as lead plaintiff.

2. Plaintiff did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.

3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. Plaintiff has made the following transaction(s) during the Class Period in the securities that are the subject of this action:

Security	Transaction	Date	Price Per Share

See attached Schedule A.

5. (a) Plaintiff has been appointed to serve as a representative party for a class in the following actions filed under the federal securities laws within the three-year period prior to the date of this Certification:

City of Birmingham Firemen's and Policemen's Supplemental Pension System v. Credit Suisse Group AG, et al., No. 1:17-cv-10014 (S.D.N.Y.)
Barry v. Colony NorthStar, Inc., et al., No. 2:18-cv-002888 (C.D. Cal.)

(b) Plaintiff is seeking to serve as a representative party for a class in the following actions filed under the federal securities laws:

None.

(c) Plaintiff initially sought to serve as a representative party for a class in the following actions filed under the federal securities laws within the three-year period prior to the date of this Certification:

Wigginton v. Advance Auto Parts, Inc., et al., No. 1:18-cv-00212 (D. Del.)
Lopes v. Fitbit, Inc., et al., No. 3:18-cv-06665 (N.D. Cal.)
Lu v. Align Technology, Inc., et al., No. 5:18-cv-06720 (N.D. Cal.)

6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 10th day of May, 2019.

TEAMSTERS LOCAL 710 PENSION FUND

By: Brian J. O'Malley
Brian J. O'Malley, Administrator

SCHEDULE A

SECURITIES TRANSACTIONS

Stock

Date Acquired	Amount of Shares Acquired	Price
11/22/2016	5,184	$90.04
12/02/2016	5,025	$88.02
08/04/2017	9,288	$114.77
11/15/2017	25,324	$102.06
01/24/2018	1,977	$110.65
02/21/2018	13,195	$104.02

Date Sold	Amount of Shares Sold	Price
08/31/2016	177	$99.93
04/20/2017	10,950	$110.07
06/07/2017	22,535	$122.04
06/22/2017	100	$119.71
06/22/2017	317	$119.71
06/23/2017	147	$119.58
06/28/2017	76	$118.93
08/07/2017	117	$115.86
02/26/2018	223	$106.68

*Opening position of 45,707 shares.

Bonds

Date Sold	Type of Debt	Face Amount	Price
01/23/2017	3.25% due 11/10/2024	230,000	$100.53
03/22/2017	3.25% due 11/10/2024	100,000	$100.53